

**EFFICACY OF DEXAMETHASONE VERSUS
TRIAMCINOLONE INJECTION IN PATIENTS
WITH CARPAL TUNNEL SYNDROME,
A RANDOMIZED CONTROL TRIAL**



THESIS

Submitted to

All India Institute of Medical Sciences; Jodhpur

In partial fulfillment of the requirement for the degree of

DOCTOR OF MEDICINE (MD)

(PHYSICAL MEDICINE AND REHABILITATION)

JUNE, 2022

AIIMS, JODHPUR

DR. MERRIN MERIA MATHEW

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DECLARATION



I hereby declare that the thesis titled **“Efficacy of Dexamethasone Versus Triamcinolone Injection in Patients with Carpal Tunnel Syndrome, A Randomized Control Trial”** embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

DR. MERRIN MERIA MATHEW

DEPARTMENT OF PHYSICAL MEDICINE AND REHABILITATION
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
JODHPUR



All India Institute of Medical Sciences, Jodhpur

CERTIFICATE

This is to certify that the thesis titled **“Efficacy of Dexamethasone Versus Triamcinolone Injection in Patients with Carpal Tunnel Syndrome, A Randomized Control Trial”** is the bonafide work of Dr. Merrin Meria Mathew, in the Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Jodhpur.

Dr. Abhay Elhence

Professor and Head

Department of Physical Medicine and Rehabilitation

AIIMS, Jodhpur



All India Institute of Medical Sciences, Jodhpur

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Guide:

Dr. Ravi Gaur

Associate Professor

Department of Physical Medicine and Rehabilitation

AIIMS, Jodhpur



All India Institute of Medical Sciences, Jodhpur

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Co-Guides:

DR. NITESH GONNADE

Associate Professor, Department of Physical Medicine and Rehabilitation

All India Institute of Medical Sciences, Jodhpur

DR. PUSHPINDER KHERA

Additional professor and Head, Department of Radiology

All India Institute of Medical Sciences, Jodhpur

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“Alone we can do so little, together we can do so much”

-Helen Keller

Nothing worth achieving has ever been achieved without proper guidance of our teachers and support of family and friends.

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LIST OF ABBREVIATIONS

CTS	Carpal Tunnel Syndrome
CTD	Cumulative Trauma Disorders
ICD-10	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
WHO	World Health Organization
VAS	Visual Analogue Scale
BCTQ	Boston Carpal Tunnel Questionnaire
NCS	Nerve Conduction Studies
SNCV	Sensory Nerve Conduction Velocity
DML	Distal Motor Latency
DSL	Distal Sensory Latency
CSA	Cross-sectional area
NSAIDs	Non-steroidal Anti-Inflammatory Drugs
AAOS	American Academy of Orthopedic Surgeons
HIF-1 α	Hypoxia-Inducible Factor 1 α
VEGF	Vascular Endothelial Growth Factor
US	Ultrasound
SNOSE	Sequentially Numbered Opaque Sealed Envelopes
NCV	Nerve Conduction Velocity
SD	Standard Deviation
BMI	Body Mass Index

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Summary of Project

Background: There is no guideline which corticosteroid has to be used as the standard treatment for Carpal Tunnel Syndrome (CTS). Triamcinolone (commonly used, particulate steroid) and Dexamethasone (non-particulate steroid with a better safety profile) are being compared for their efficacy in CTS.

Aim: To compare the efficacy of Dexamethasone and Triamcinolone injection in patients with CTS.

Methods: Mild-moderate cases of CTS, confirmed by Nerve Conduction Studies (NCS), with symptoms lasting more than 3 months, were recruited and randomized into two groups- Dexamethasone and Triamcinolone group. Participants received one-session of ultrasound-guided perineural injection by in-plane axial ulnar sided approach with 4ml of either Dexamethasone sodium phosphate [8mg (2ml) + 2 ml 0.5% bupivacaine] or Triamcinolone acetone [40mg (1ml) + 2ml 0.5% bupivacaine + 1ml normal saline] solution according to the randomized group of the patient. The estimated sample size was 72 (36 in each group). Phalen's test time, VAS score and BCTQ score were recorded at baseline, 2 months and 4 months after the injection. NCS was done at baseline and after 4 months. Statistical analysis was done using IBM-SPSS software version 26. Independent-Samples t-test was used for comparison between groups and paired t test for improvement within each group. A p value < 0.05 was considered statistically significant.

Results: A total of 69 patients completed the study (33 in the Dexamethasone group and 36 in the Triamcinolone group). Phalen's test time significantly improved within both Dexamethasone and Triamcinolone groups from mean 33.73 ± 8.304 at baseline to 51.45 ± 5.154 at 2nd month ($p < 0.05$) and 42.88 ± 3.806 at 4th month ($p < 0.05$) after Dexamethasone injection and from 35.5 ± 8.687 at baseline to 52.81 ± 4.845 at

2nd month ($p < 0.05$) and 43.22 ± 4.817 at 4th month ($p < 0.05$) after Triamcinolone injection. There was also significant improvement in VAS score ($p < 0.05$), BCTQ score ($p < 0.05$) and NCS changes ($p < 0.05$) at 4th month within each group. However, there was no significant difference between the two groups in any of the assessed parameter. Local post- procedure pain lasted significantly longer in the triamcinolone group compared to dexamethasone group ($p < 0.05$).

Conclusion: Dexamethasone is as effective as Triamcinolone in improving the symptoms of CTS.

INTRODUCTION

INTRODUCTION

Carpal Tunnel Syndrome (CTS) is a disorder that falls under the broad heading of Cumulative Trauma Disorders (CTD), which is a term for various injuries of the musculoskeletal and nervous systems, that are caused by repetitive tasks, forceful exertions, vibrations, mechanical compression or sustained postures(1).

CTS is one such disabling, and distressing, work-related musculoskeletal disorder common among manual workers, which accounts for 90% of all peripheral entrapment neuropathy (2).

CTS affects the day-to-day activities of the affected population and the associated healthcare costs contribute to a significant socioeconomic burden in the society, both in terms of the productivity lost and the costs of treatment (3).

ICD-10 Classification of Diseases assigns the Diagnosis Code G56.0 for CTS. (4)

International Classification of Functioning, Disability and Health (ICF) has described the impairments, activity limitations and participation restrictions in carpal tunnel syndrome as under:

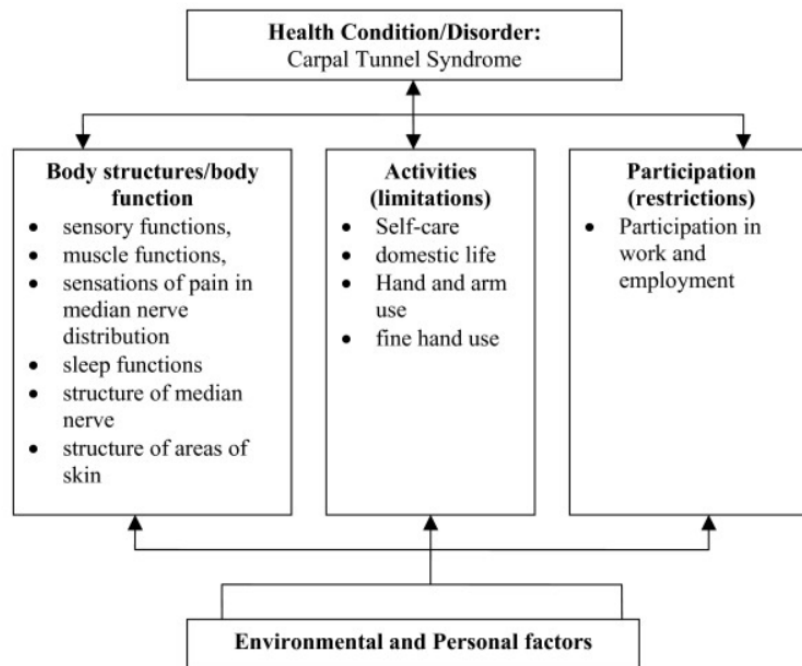


Figure 1: Interaction of concepts of the ICF in CTS (adapted from ICF, WHO 2002)

RELEVANT ANATOMY:

The carpal tunnel is a space enclosed by carpal bones on three sides and flexor retinaculum on the fourth side. The volume of carpal tunnel is around 5-6 mL (5) with little room for expansion or swelling due to its inelastic borders. The carpal tunnel is traversed by 9 tendons (4 flexor digitorum superficialis tendons, 4 flexor digitorum profundus tendons, and tendon of flexor pollicis longus) and the median nerve. Median nerve supplies sensation to radial 3 ½ fingers, 1st and 2nd lumbricals and the thenar musculature. Palmar cutaneous branch of Median nerve which supplies sensation to the volar base of the thumb and radial side of the palm, branches off proximal to the carpal tunnel due to which it is not affected by compression in the carpal tunnel, and thus helps to distinguish CTS from the more proximal median neuropathy. The recurrent branch of the median nerve innervates the opponens pollicis, abductor pollicis brevis, and the superficial part of the flexor pollicis brevis. (6)

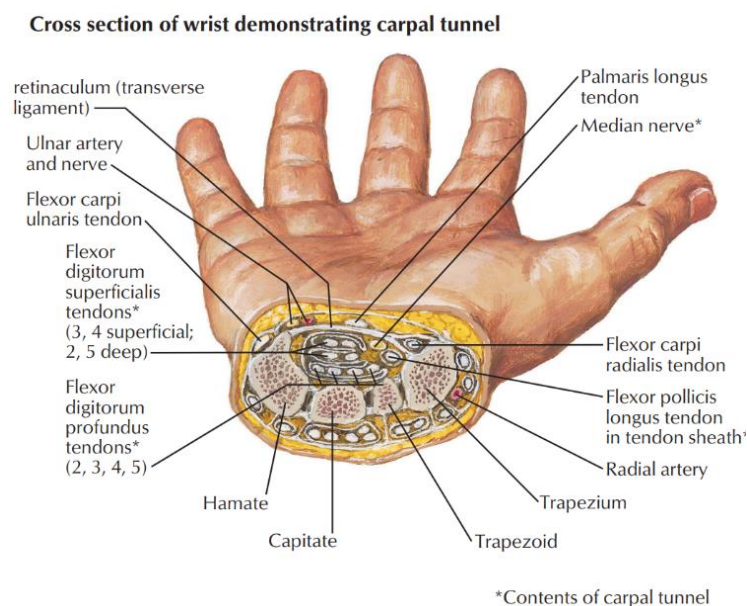


Figure 2: Anatomy of carpal tunnel (Taken from Netters Atlas of Human Anatomy 6th edition pg.452)

EPIDEMIOLOGY

Incidence of CTS was found to be 276 per 100,000, with the incidence rates being 9.2% in women and 6% in men (7). The overall prevalence in the general population was estimated to be at ~3.8%. (8) CTS is markedly more common in females than in males and is mostly bilateral with peak incidence in the age group of 40-60 years. (9)

RISK FACTORS (10)

1) Ecological risk factors:

- a) Extended positions in excesses of wrist flexion or extension
- b) Monotonous use of the flexor muscles
- c) Exposure to vibration

2) Medical risk factors:

- i. Extrinsic factors: Factors which increase body fluid volume like pregnancy, menopause, obesity, renal failure, hypothyroidism, use of oral contraceptives, and congestive heart failure
- ii. Intrinsic factors: Lumps, tumor, radial fractures or posttraumatic arthritis etc. that increase volume within the tunnel.
- iii. Extrinsic factors that alter the contour of the tunnel
- iv. Neuropathic factors: Conditions like diabetes, alcoholism, vitamin deficiency or toxicity, and toxin exposure affecting median nerve without increasing the pressure within the carpal tunnel.

CLINICAL FEATURES:

CTS is characterized by hand pain, numbness, and tingling sensation in the sensory distribution of median nerve (radial 3 ½ fingers) along with a reduction in grip strength and hand function (11,12). Patients commonly complain of a nocturnal worsening of symptoms, worsening of symptoms while driving, holding a handset, gripping etc. and hand clumsiness during daytime with activities requiring wrist flexion(13). The numbness is aggravated by activities such as typing, driving, or knitting and nocturnal dysesthesia interrupts sleep and is relieved by shaking or flicking the hand, referred to as the 'flick sign'(14).

DIAGNOSIS

Diagnosis requires a thorough history of symptom onset, provocative factors, work activity, pain localization and radiation, maneuvers that alleviate the symptoms and presence of predisposing factors like diabetes, obesity, chronic polyarthritis, myxedema, acromegaly, pregnancy, sports activities etc. (15) The two provocative tests used most commonly are the Phalen's test (85% sensitivity and 90% specificity) (9), Tinel's test (62% sensitivity and 93% specificity)(16) and carpal tunnel compression test (87% sensitivity and 90% specificity) (17).

Other tools for severity assessment include Visual Analogue Scale (VAS), Positive Phalen's test time in seconds, Boston Carpal Tunnel Questionnaire (BCTQ) etc. Phalen's test time is assessed by making the patient actively place both the wrists into forced palmar flexion against each other, so that the pressure inside the carpal tunnel increases and the paresthesia symptoms are reproduced and the time of appearance of paresthesia noted in seconds. Cunha et al. suggested positive phalen's test time <10 seconds to have severe CTS; between 10 to 30 seconds to have moderate CTS and >30 seconds to have mild CTS clinically(18). BCTQ is a questionnaire developed by Levine et al. in 1993 which consists of 2 scales- a Symptom severity scale (11 items each scored between 1-5 according to the severity) and Functional Status scale (8 items each scored 1-5 based on difficulty performing the task) (19).

These should be followed by appropriate Nerve Conduction Studies (NCS) which is considered the Gold standard in the diagnosis of CTS (20).

The NCS diagnostic criteria for CTS are prolongation of motor and sensory latencies along with reduced sensory and motor conduction velocities of the median nerve (21).

Table 1: Abnormal NCS cut-off values are:

Sensory Nerve Conduction Velocity (SNCV)	<50m/s
Distal Motor Latency (DML)	>4.3ms
Distal Sensory Latency (DSL)	>3.6ms
Amplitude (sensory)	<10 uV
Amplitude (motor)	< 5 mV

Table 2: American Association of Neuromuscular and Electrodiagnostic Medicine Grading of CTS based on NCS finding (21):

CTS grade	NCS finding
Minimal	Abnormal segmental or comparative tests only
Mild	Abnormal Sensory Nerve Conduction Velocity (SNCV) only with normal DML
Moderate	Abnormal SNCV and abnormal DML
Severe	Absent sensory response and abnormal DML
Extreme	Absence of motor and sensory responses

Another helpful diagnostic tool is Ultrasound assessment of the median nerve in the carpal tunnel. The Ultrasonographic diagnostic features of CTS are thickening of the median nerve and flattening of the nerve within the tunnel (22). Cross-sectional area (CSA) of the median nerve $\geq 10\text{mm}^2$ is diagnostic of CTS (23).

El Miedany et al. recommended ultrasound cut-off points that discriminate between different grades of CTS severity (23) as shown in Table 3.

Table 3: CTS grading based on CSA of median nerve measured using ultrasound

Grade	CSA of median nerve
Mild CTS	10.0–13.0 mm ²
Moderate CTS	13.0–15.0 mm ²
Severe CTS	>15.0 mm ²

TREATMENT

According to *LeBlanc et al (2011)* and *Piazzini et al*, CTS should be managed based on the severity of disease. In mild disease, 6 weeks to 3 months of conservative treatment is recommended as first line.(24)

Patients are initially prescribed Non-steroidal Anti-Inflammatory Drugs (NSAIDs) concurrently with physical therapy and hand splints. If the outcome is unsatisfactory with not much improvement in their symptoms, then, a steroid injection into the carpal tunnel, preferably under Ultrasound guidance is indicated. In moderate to severe disease, or those having persistent symptoms despite conservative treatment, may need surgical treatment.(25–28)

The most popular and commonly used corticosteroid for this purpose is Triamcinolone Acetonide, which is a particulate steroid and has demonstrated positive treatment outcome (28) but has possibility of more side effects due to its particulate nature. Dexamethasone on the other hand is a non-particulate steroid with a better safety profile (29). In this study, we are comparing the efficacy of perineural injection of these two steroids administered under ultrasound guidance in CTS.

***REVIEW OF
LITERATURE***

REVIEW OF LITERATURE

CTS is defined by AAOS as “A symptomatic compressive neuropathy of the median nerve at the level of the wrist.”

CTS is caused by increased pressure in the carpal tunnel with compression of median nerve leading to gradual ischemia, impaired neural conduction and damage of the median nerve (30,31).

Aboong MS et al in 2015 studied the pathophysiology of CTS and the schematic representation of the same is illustrated in figure 1.

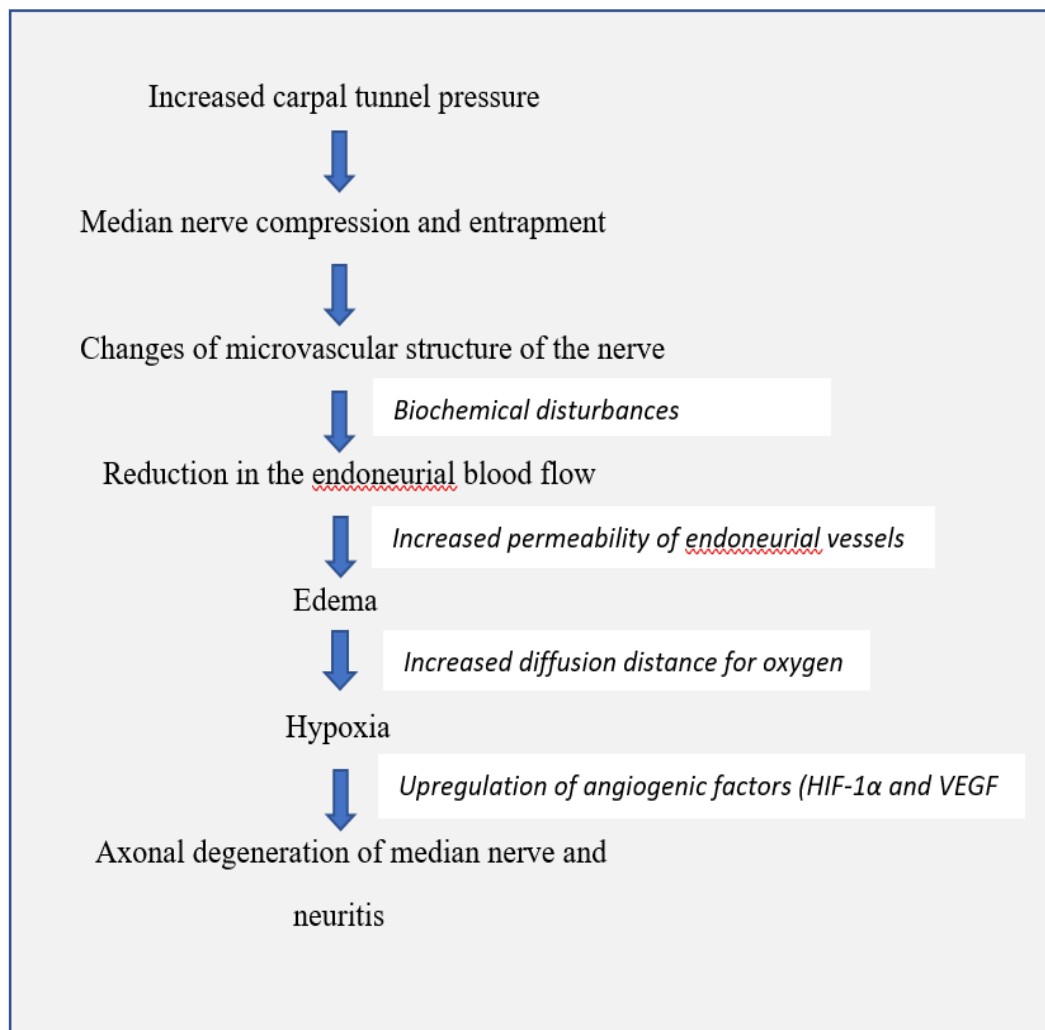


Figure 3: Pathophysiology of CTS- A schematic presentation for vascular mechanism of CTS and median nerve injury. HIF-1α - hypoxia-inducible factor 1α, VEGF - vascular endothelial grown factor (32)

A variety of conditions produce somewhat similar symptoms to those of CTS (as shown in Table 4) (33):

Table 4: Differential Diagnosis of CTS

Condition	Characteristic
Carpometacarpal arthritis of thumb	Joint line pain, pain on motion, radiologic finding
C6 Cervical radiculopathy	Neck pain, numbness in thumb and index finger only
Flexor carpi radialis tenosynovitis	Tenderness near base of thumb
Median nerve compression at elbow	Tenderness at the proximal forearm
Raynaud phenomenon	History of symptoms related to cold exposure
Ulnar or Cubital tunnel syndrome	First dorsal interosseous weakness, 4 th and 5 th digit paresthesia
Vibration white finger	Use of vibrating hand tools at work
Volar radial ganglion	Mass near base of thumb, above wrist flexion crease
Wrist arthritis	Limited motion at wrist, radiologic finding

A condition worth mentioning is Double Crush Syndrome in which axons compressed at one site become especially susceptible to damage at another site.

Upton and McComas used the double crush syndrome to explain why patients with CTS sometimes feel pain in the forearm, elbow, arm, shoulder, chest, and upper back. They also used it to explain failed attempts at surgical repairs when neither surgery nor CTS diagnosis appeared faulty. They claimed that most patients with CTS not only have compressive lesions at the wrist, but also show evidence of damage to cervical nerve roots. (34)

Jerosch-Herold C. et al. in their study found that patient reported symptom severity in CTS was significantly and positively associated with anxiety, depression and a decreased health related quality of life (35).

Despite this, there is much controversy regarding the optimal therapy for CTS.

Martins et al. in a review on the conservative management of CTS states that the first therapeutic option in patients without significant sensory or motor deficits is always

conservative treatment. Recommendations include- avoiding repetitive motions, using proper ergonomic equipment (like wrist rest, mouse pad), taking timely breaks, using keyboard alternatives (like digital pen, voice recognition, dictation software etc.), alternating job functions etc. But there is inconsistent evidence to support or refute the effectiveness of any of these interventions.(32)

About the oral medications, oral corticosteroids produce significant short-term symptomatic relief, with benefits waning off over a period of 8 weeks after discontinuation. Nonsteroidal anti-inflammatory drugs (NSAIDs), diuretics, and pyridoxine (vitamin B6) were however, though used frequently, not found to be more effective than placebo.(32)

Evidence supports the use of neutral and cock-up wrist splints, both having similar efficacy. It is recommended to use these splints full time (24 hrs) over nocturnal use alone(36). Although there is little evidence regarding the recommended splinting duration, most studies have used splinting for 6-8 weeks, but its effectiveness has been noted up to 1 year.

In case of not achieving significant relief with splints and oral medications alone, **AAOS guidelines** recommend the use of local steroid injection before considering surgery but there is no guideline regarding which corticosteroid is to be used as the standard treatment for CTS. (27)

CTS is known to be associated with marked inflammation and edema of the synovial tissue of flexor tendons. Corticosteroid injection into the carpal tunnel help reduce this inflammation and edema which is the main reason for their efficacy in reducing the symptoms of CTS (37,38).

Piazzini et al. (2007) in a systematic review on conservative treatment of CTS also concluded in favour of using local corticosteroid injection in CTS which was effective in providing significant improvement of symptoms (25).

Peters-Veluthamaningal et al (2010) also found that corticosteroid injections given for CTS was effective compared to placebo injections (39).

Ertem et al. (2019) also found that local corticosteroid injection provides short-term improvement in neurophysiological and clinical outcomes such as pain intensity, symptom severity and functional ability (40).

In their study, **Marshall et al.** showed that local corticosteroids offered greater symptom relief than oral steroids for up to 3 months. (28)

Chesterton et al (2018) compared the clinical and cost-effectiveness of corticosteroid injection with that of night splints in patients with mild to moderate CTS and showed that a single corticosteroid injection had superior clinical effectiveness at 6 weeks than resting night splints, making it the treatment of choice for rapid symptom response in mild to moderate CTS (41).

So et al. (2018) also compared the efficacy of local steroid injection and nocturnal wrist splinting in patients with CTS and found that though both are effective in the treatment of CTS, only the steroid injection improved objective hand function with better patient satisfaction and less painkiller use post-procedure, without causing significant side effects (42).

But prior to injecting local corticosteroids for CTS, one should be aware of the possible side effects it can cause.

According to *Martins et al.*, most common risks associated with carpal tunnel injection are nerve and/or tendon injuries. Inadvertent injection into the median nerve can cause immediate shock-like pain, sensory and/or motor deficits along with persistent neuropathic pain. Corticosteroid injections are to be avoided in patients with uncontrolled diabetes. Some patients may experience temporary worsening of pain which can last for 2-3 days after the injection. Manual work should be avoided for at least 1-2 days after the procedure. They have concluded that steroid injection can be repeated after 1-3 months but not more than 2-3 times due to the potential side effects. (32)

But in another study, they have suggested that repeat injection in the same wrist should be considered only after 6 months and that if symptoms recur after two injections, surgery may have to be considered. (43)

Evers et al (2017) conducted a long-term follow-up in a population based cohort study for a median follow-up duration of 7.4 years to determine the re-intervention rate and found that 32% patients did not need subsequent treatment after a single injection of corticosteroid into the carpal tunnel. (44)

Visser et al. (2012) conducted a study to assess the long term effect of local corticosteroid injection and the prognostic factors for its long-term efficacy and concluded that patients with an electro-diagnostically mild CTS (i.e., abnormal comparative tests or prolonged median DSL>3.5 ms but normal median DML) are good candidates for local steroid injection with half of them having a good long term effect for even more than 15 months (45).

Jenkins et al (2012) in a similar study found that the overall 5-year rate of secondary carpal tunnel decompression after initial local corticosteroid injection was 15% at 1 year and 33% at 5 years. The need for secondary carpal tunnel decompression was also found to be higher in females, those with diabetes mellitus and those who had positive NCS at diagnosis (46).

Regarding the injection approach, available evidence does not favour one injection technique over another or a particular steroid formulation. However, ultrasound-guided injection is better and more effective than blind injection as it allows direct visualization to ensure accurate and safe needle placement. Although generally safe, there is always a risk of injury to median nerve and/or tendon rupture which needs to be kept in mind.

Lee et al. (2014) concluded that US-guided local steroid injection using an in-plane ulnar approach is more effective than out-plane or blind injection with significant improvement in BCTQ and NCS parameters at 4 weeks after ultrasound guided steroid injection by in-plane ulnar approach (47).

Some studies compared the efficacy of conservative treatment options with that of surgery and found that, surgical treatment of CTS relieves symptoms significantly more than splinting, but not necessarily more than corticosteroid injection.(48)

Green et al. (1984) found that after a steroid injection, 81% of the patients obtained good or complete relief lasting for up to 45 months. Symptoms would sometimes recur after about 2 to 4 months (average 3.3 months), but recurrence was not severe enough to warrant surgical treatment. (49).

Ly-Pen et al. (2005) also compared the efficacy of local steroid injection and surgical decompression in new-onset CTS of at least 3 months duration and found that the steroid injection was better than surgery for short-term relief of CTS while at 1 year, both were equally effective (50).

There is still no consensus regarding which corticosteroids are preferred for local injection in CTS.

However, there was one important animal experimental study by **Mackinnon et al. (1982)** on the neurotoxicity of various steroids, and they reported that triamcinolone caused widespread axonal and myelin degeneration while dexamethasone was the least neurotoxic agent. Due to the physical properties of Triamcinolone like water-insolubility, white sediment formation and crystallization at the injection site, if a physician accidentally injects triamcinolone directly into the nerves, it can cause

permanent nerve injury with axonal and myelin degeneration which could lead to median nerve palsy. Dexamethasone sodium phosphate, on the other hand, is clear and water soluble with no crystallization property due to which even if accidentally injected into the nerve, the nerve injury can resolve spontaneously (29).

Some studies independently assessed the efficacy and side effect profile of each of Triamcinolone and Dexamethasone injections in CTS.

Kaile and Bland (2017) studied the safety of triamcinolone 40mg injection for CTS and reported side effects only after 33% of injections, the commonest being short-lived local pain in 13% of injected limbs and all cases resolved within 3 weeks. No case of intraneural injection or tendon rupture occurred, even after repeated injection. Though most adverse effects were transient, 13 hands developed persistent skin depigmentation or subcutaneous atrophy after triamcinolone injection (51).

Niempoog et al. (2007), proved that dexamethasone was effective in controlling the symptoms of CTS in pregnant women (52).

Moghtaderi et al. (2011) also found that local dexamethasone injection in pregnant women with CTS significantly improved the pain intensity and electrophysiological parameters post-injection without any complications(53).

There is currently only one study (a randomized control study), comparing the efficacy of Triamcinolone and Dexamethasone injection in CTS which was conducted by **Dilokhuttakarn et al. (2018)**. They concluded that dexamethasone sodium phosphate was effective in CTS with significant improvement in positive Phalen's test time, compared to those treated with triamcinolone acetone, with no serious complications detected in either group (54).

There are no similar studies comparing Dexamethasone and Triamcinolone injections in CTS in the Indian setting as per our knowledge and hence this study was proposed and planned.

AIMS AND OBJECTIVES

Aim – To compare the efficacy of Dexamethasone and Triamcinolone acetonide injection in patients with carpal tunnel syndrome.

Objectives –

1.Primary: To compare the Positive Phalen's test time (in seconds) in each group at 0, 2 and 4 months.

2. Secondary:

1. To compare the pain relief obtained in each group using Visual Analogue Scale (VAS) at 0, 2 and 4 months.
2. To compare the improvement in Boston Carpal Tunnel Questionnaire (BCTQ) score in each group at 0, 2 and 4 months
3. To observe the changes in the Nerve Conduction Studies (NCS) at 0 and 4 months.

Research Question- Is Dexamethasone an effective alternative to Triamcinolone injection in carpal tunnel syndrome?

Null Hypothesis – There is no significant difference in the efficacy of perineural injection with Dexamethasone and Triamcinolone in carpal tunnel syndrome.

Alternate Hypothesis- There is significant difference in the efficacy of perineural injection with Dexamethasone and Triamcinolone in carpal tunnel syndrome.

***MATERIALS AND
METHODS***

METHODOLOGY:

Study setting – Out Patient clinic in the Department of Physical Medicine and Rehabilitation at All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Study design – Open label, parallel-design, randomized control trial.

Study participants – All patients diagnosed with carpal tunnel syndrome attending outpatient clinic in the Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Jodhpur, Rajasthan from January 2020 to December 2021 and satisfying the following inclusion criteria were enrolled in the study.

Inclusion criteria:

- Age between 20-80 years.
- Mild-Moderate cases of CTS, confirmed by electrophysiological tests, with symptoms lasting for a minimum of 3 months.

Exclusion criteria:

- Malignancies
- Cervical radiculopathy
- Brachial plexopathy
- Thoracic outlet syndrome
- Infections
- Inflammatory joint and connective tissue disorders
- Uncontrolled Diabetes
- Burns/ Any local Tissue contractures
- History of wrist trauma/ surgery

Sampling and sample size:

Dilokhuttakarn et al 2018 reported an overall Positive Phalen's test time at 2 months follow-up with a mean value of 52.00 with a standard deviation of 11.42 in Dexamethasone group and a mean value of 42.33 with a standard deviation of 16.95 in Triamcinolone group. Considering this for sample size calculation, we estimated a

sample size of 36 in each group at 95% confidence interval and 80% power. Thus, a total of 72 patients of CTS were to be recruited and randomized into two groups.

Study duration – January 2020 to December 2021

Methodology and Data Collection

Scientific Committee and Institute Ethics Committee approval was taken prior to commencement of the study. All patients satisfying the inclusion and exclusion criteria during the study period were considered eligible for participation. A written informed consent was taken from all participants. Patients clinically diagnosed with CTS and confirmed by electrophysiological studies, were randomized into Dexamethasone and Triamcinolone group using the SNOSE (Sequentially Numbered Opaque Sealed Envelopes) technique for allocation concealment followed by block randomization using block sizes of 4 and 5. This was an open label trial where patients were not blinded to their allocated treatment. All patients, irrespective of the group allotted, received the basic conservative management with hand splint, medications like Gabapentin (300 – 600mg), NSAIDs, Paracetamol (up to maximum 4g/day), nerve and tendon gliding exercises etc. (AAOS Guidelines). In addition, participants in Dexamethasone group received one-session of ultrasound-guided perineural injection with 4ml [Dexamethasone sodium phosphate 8mg (2ml) + 2 ml 0.5% bupivacaine] and those in Triamcinolone group received one-session of ultrasound-guided perineural injection with 4ml [Triamcinolone acetonide 40mg/ml (1ml) + 2ml 0.5% bupivacaine + 1ml normal saline]. Demographic, clinical and procedural details of all patients undergoing the procedure, including any adverse reactions were noted. Ultrasonography was done using Sonosite S II ultrasound machine and Nerve Conduction Velocity (NCV) was assessed using Nihon Kohden EMG/EP Measuring System Model MEB-2300K SN 00202. The participants were instructed to refrain from all other treatments for CTS throughout the study period.

The entire procedure was conducted under ultrasound guidance following all aseptic precautions in accordance with the standard perineural injection protocol as follows:

Injection Technique: In-Plane Axial Ulnar Sided Approach

Patient positioning: Patient was asked to sit with the affected arm resting comfortably on the table. A rolled towel was placed underneath the wrist to create mild extension.

Probe position: The transducer was placed short axis (transverse) to the median nerve at the wrist.

Scan was done proximally and distally until the nerve is clearly identified under the transverse carpal ligament, at approximately the level of the pisiform.

Markings: Because of the shallow needle plane angle, the ulnar nerve and artery were identified, and the needle was inserted just radial or deep to these structures.

Needle position: The 23 G, 1-inch needle was inserted on the ulnar side of the wrist crease parallel to the transducer for optimal needle visualization using in-plane approach.

Then either 2ml (8mg) Dexamethasone sodium phosphate combined with 2 ml 0.5% bupivacaine (Group D/Dexamethasone group) or 1ml (40mg) Triamcinolone acetone combined with 2ml 0.5% bupivacaine and 1ml normal saline (Group T/Triamcinolone group) making up a total of 4ml solution was injected in the carpal tunnel, around the median nerve, depending on the randomized grouping of the patient.

Sample size being 72, 36 patients were expected to be in each group D and T.

The primary outcome assessed was Positive Phalen's test time and secondary outcomes include Visual Analogue Scale (VAS) scored from 0(no pain) to 10(unbearable pain), Boston Carpal Tunnel Questionnaire (BCTQ) score and Nerve Conduction Study (NCS) changes of the median nerve. The evaluation for Positive Phalen's test time, VAS and BCTQ score was performed pretreatment (0) as well as 0 2 and 4 months after the injection. NCS was evaluated at 0 and 4 months after injection.

STATISTICAL ANALYSIS

Data was entered in Microsoft Excel and analysis was done using IBM SPSS version 26. The Quantitative variables like Age, Positive Phalen's test time, VAS score etc. were described using mean and standard deviation. Independent-Samples t-test was used for comparison between groups and paired t test for improvement within each group. A p value < 0.05 was considered statistically significant.

RESULTS

RESULTS

During the study period, a total of 72 patients who were clinically diagnosed with CTS and confirmed by electrophysiologic studies who met the inclusion criteria and did not meet the exclusion criteria were recruited for the study.

Out of the 72 recruited patients, 3 patients were lost to follow up while remaining 69 patients completed the follow up till 4 months after the procedure. The recruited patients were randomized into either the dexamethasone or the triamcinolone group using the SNOSE (Sequentially Numbered Opaque Sealed Envelopes) technique for allocation concealment followed by block randomization using block sizes of 4 and 5. Patients were not blinded to their allocated treatment. All patients received the basic conservative management with hand splint, Gabapentin (300 – 600mg), NSAIDs, Paracetamol (up to maximum 4g/day), nerve and tendon gliding exercises. After a trial with these agents alone when the patients did not improve significantly, they were given ultrasound guided perineural injection with either dexamethasone or triamcinolone solution according to the randomized group they belonged to. After the injection, participants were allowed to take only paracetamol (up to max 4g/day) and no other medications. Out of those who completed the study, 33 patients were in the Dexamethasone Group and 36 patients in the Triamcinolone group.

Figure 4 shows the analysis flow-chart of recruited participants.

Table 5 shows the demographic characteristics of the participants.

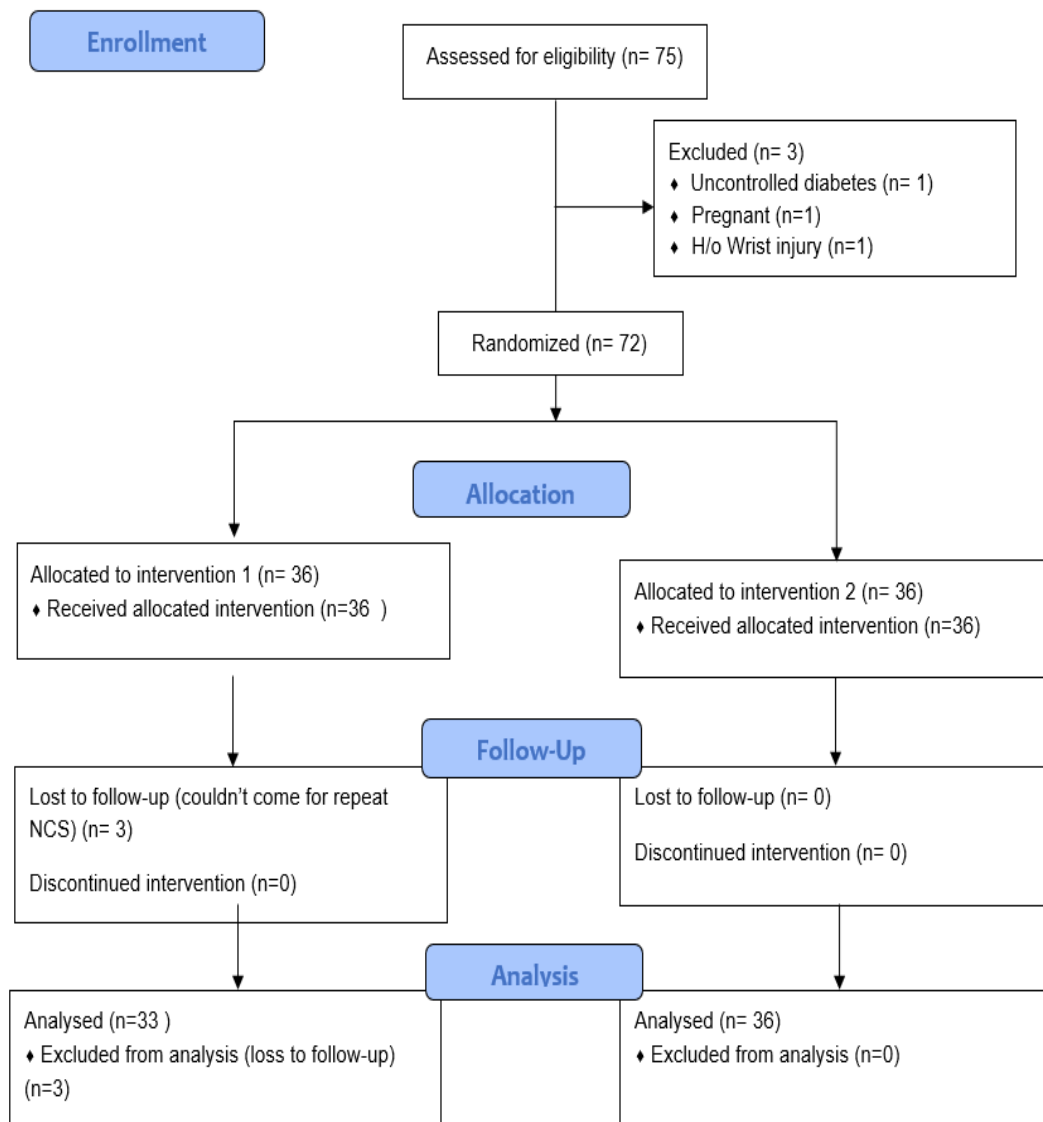


Figure 4: Analysis of recruited participants

Table 5: Demographic data of patients

	TRIAMCINOLONE (n=36)	DEXAMETHASONE (n=33)
AGE (years)		
Mean \pm SD	45.22 \pm 10.6	42.64 \pm 10.99
GENDER		
Male, n (%)	7 (19.4)	4 (12.9)
Female, n (%)	29 (80.6)	29 (87.1)
OCCUPATION n (%)		
Housewife	19 (52.8)	21 (63.7)
Manual worker	11 (30.5)	8 (24.2)
Others	6 (16.7)	4 (12.1)
DOMINANT HAND n (%)		
Right	33 (91.7)	31 (93.9)
Left	3 (8.3)	2 (6.1)
SIDE OF SYMPTOMS n (%)		
Right	19 (52.8)	19 (57.6)
Left	17 (47.2)	14 (42.4)
Dominant hand	18 (50)	19 (57.6)
Non-dominant hand	18 (50)	14 (42.4)
SEVERITY OF CTS n (%)		
Mild	22 (61.1)	15 (45.5)
Moderate	14 (38.9)	18 (54.5)

1.1 Age:

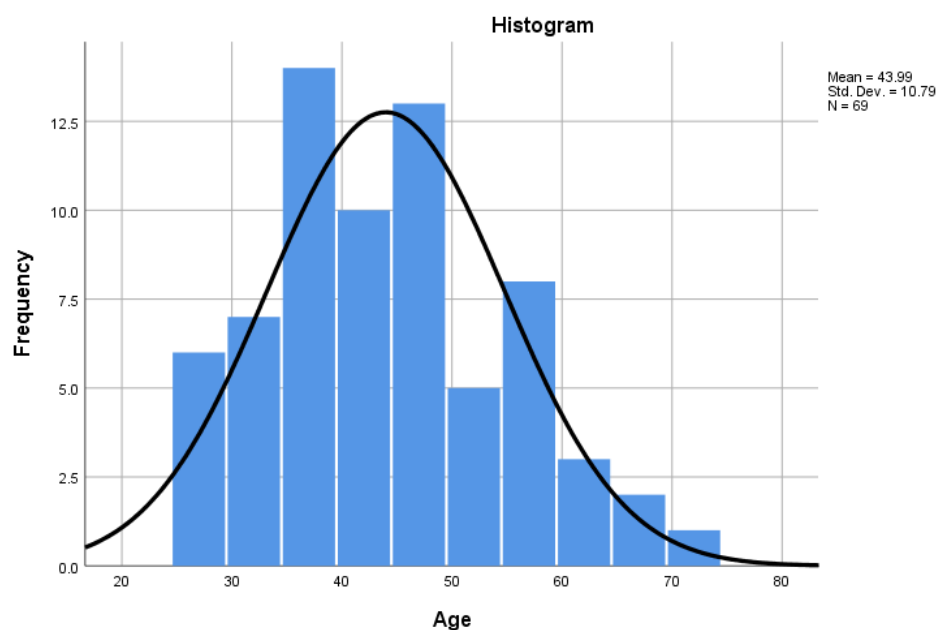


Figure 5: Distribution of age in study population

Figure 5 shows distribution of age in our study population. It is a bell-shaped curve, which signifies that age was normally distributed in the data. Mean age was 43.99 years with standard deviation of ± 10.79 .

Table 6: Comparison of age in two groups

	Mean Age (years)	Std. Deviation	<i>P</i> value*
Dexamethasone (n=33)	42.64	10.994	
Triamcinolone (n=36)	45.22	10.602	0.324

* Student *t* test

Table 6 shows that mean age in Dexamethasone group was 42.64 years ± 10.99 and in Triamcinolone group, mean age was 45.22 years ± 10.6 . Age in both groups was

compared by student's *t* test. *P* value was 0.324 which is > 0.05 and thus there is no significant difference between the age distribution in both groups.

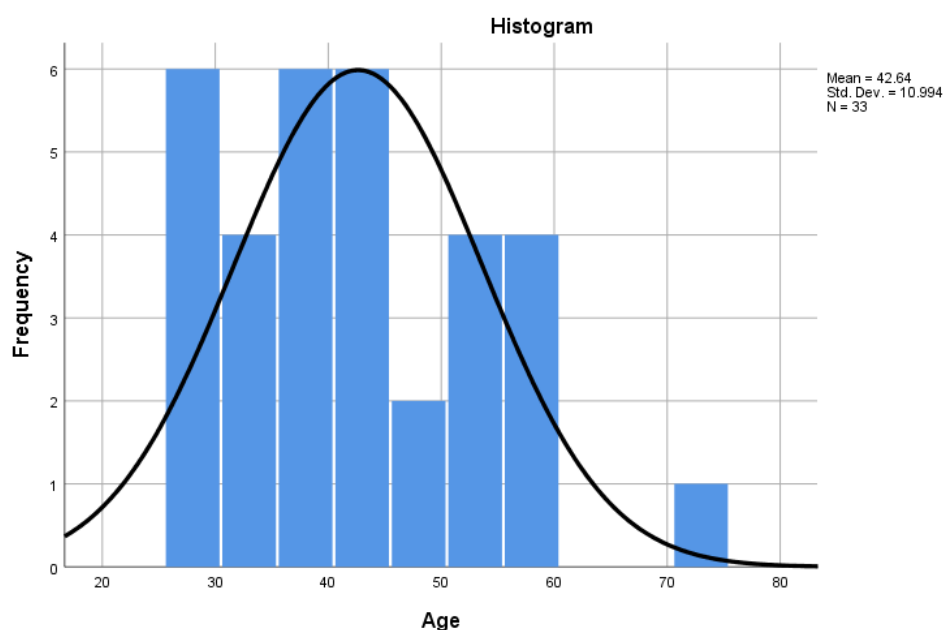


Figure 6a- Distribution of age in Dexamethasone group

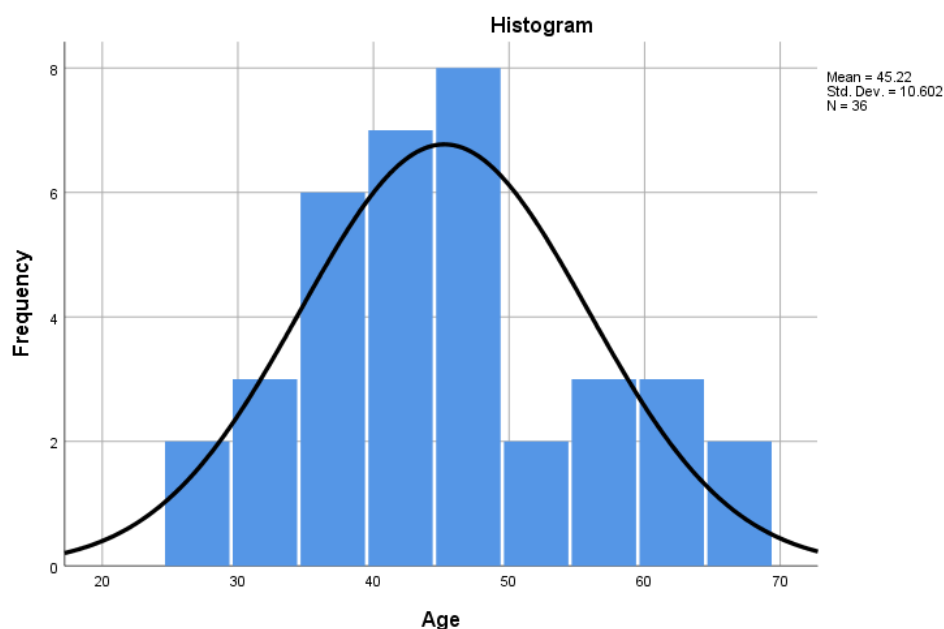


Figure 6b: Distribution of age in Triamcinolone group

Figure 6a and 6b shows distribution of age in Dexamethasone and Triamcinolone groups.

1.2 BMI:

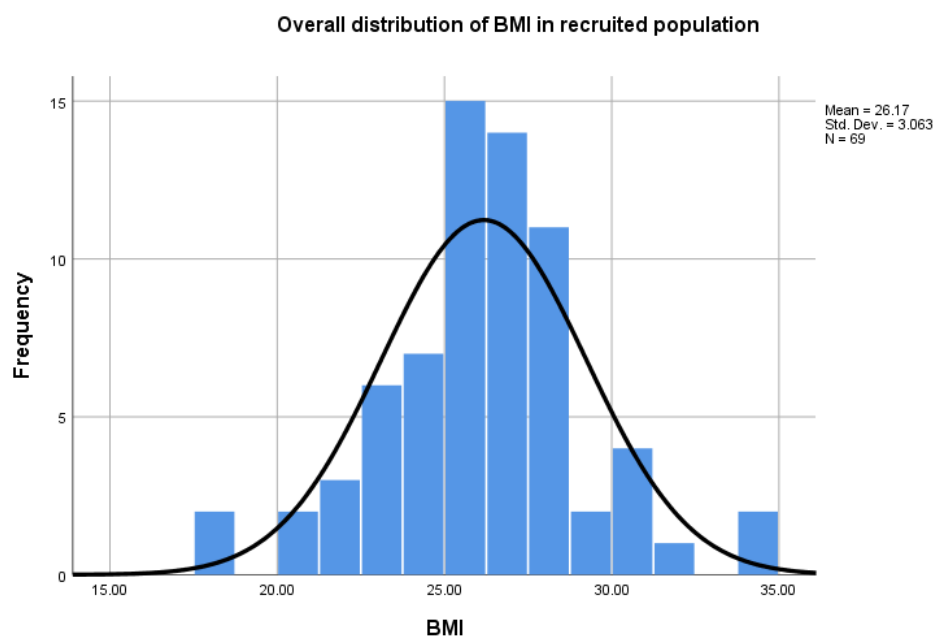


Figure 7: Overall distribution of BMI in recruited population

Figure 7 shows distribution of BMI in the study population, producing a bell-shaped curve, the mean BMI was 26.17 kg/m² with standard deviation of \pm 3.063.

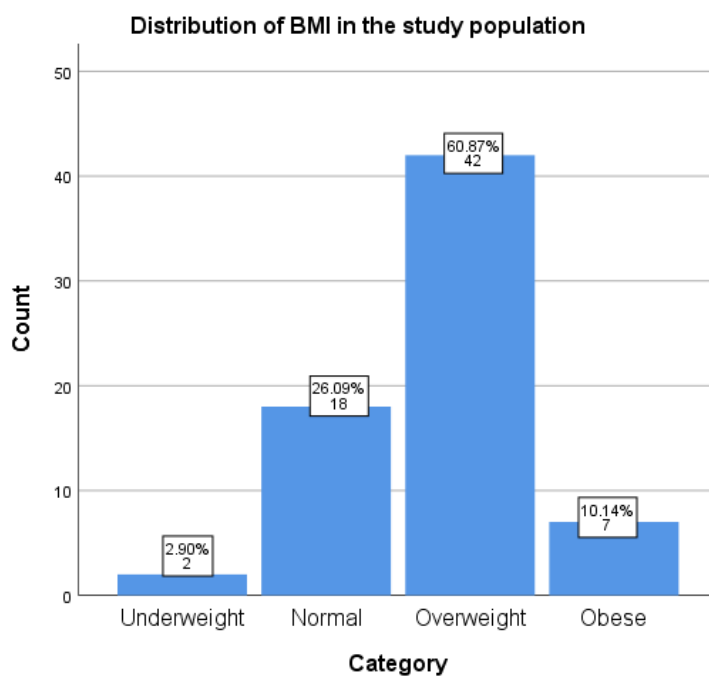


Figure 8: Categorization of the study population according to BMI

Figure 8 shows the distribution of BMI in the study population according to WHO cut-off categories. There were 2 (2.9%) underweight women, 18 (26.09%) normal, 42 (60.87%) overweight and 7 (10.14%) obese women in this population. A striking majority of patients were in the overweight category.

1.3 Gender:

Proportion of Males and Females in the Recruited population

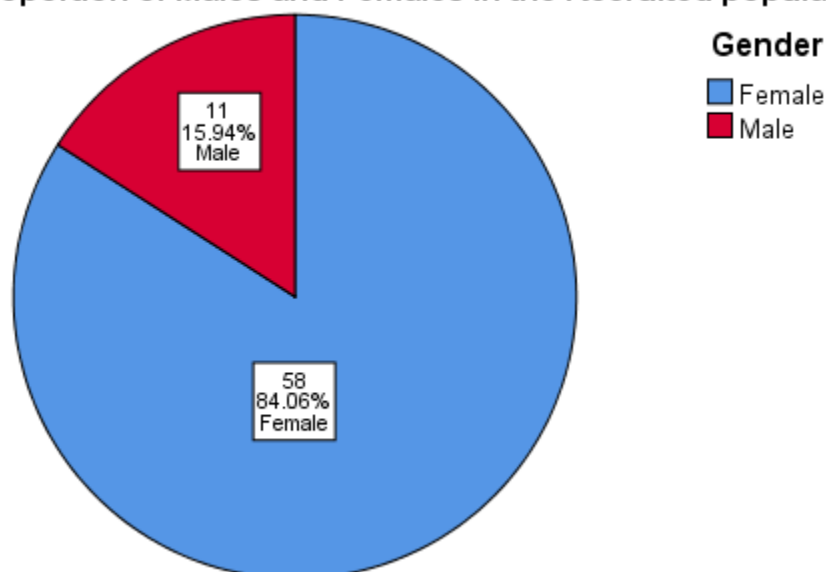


Figure 9: Distribution of Recruited population by Gender

Figure 9 shows the proportion of males and females in the study population. There were 58 females (84.06 %) and 11 males (15.94 %).

Table 7: Intra-group comparison:

Parameter	Dexamethasone group (n= 33)			Triamcinolone group (n=36)		
Phalen's test time	Mean	SD	<i>P value</i>	Mean	SD	<i>P value</i>
At Baseline	33.73	8.304		35.5	8.687	
At 2 nd month	51.45	5.154	<i>0.000</i>	52.81	4.845	<i>0.000</i>
At 4 th month	42.88	3.806	<i>0.000</i>	43.22	4.817	<i>0.000</i>
VAS score						
At Baseline	6.36	0.994		6.17	0.910	
At 2 nd month	1.85	0.870	<i>0.000</i>	1.39	1.225	<i>0.000</i>
At 4 th month	2.06	1.116	<i>0.000</i>	1.75	1.422	<i>0.000</i>
BCTQ score						
At Baseline	49.18	17.74		51.81	17.139	
At 2 nd month	21.15	3.043	<i>0.000</i>	22.78	6.551	<i>0.000</i>
At 4 th month	21.61	4.723	<i>0.000</i>	23.83	7.193	<i>0.000</i>
SNCV						
At Baseline	37.38	6.2455		39.217	6.2764	
At 4 th month	44.394	6.7027	<i>0.000</i>	45.428	6.2912	<i>0.000</i>
DML						
At Baseline	4.242	0.7150		4.244	1.1816	
At 4 th month	3.367	0.5605	<i>0.000</i>	3.300	1.0871	<i>0.000</i>

Table 7 shows the improvement observed in each group for each of the assessed parameters. As is evident from the table, *P value* for improvement at the 2nd and 4th months after injection each for Phalen's test time, VAS score, BCTQ score and the

NCS parameters (SNCV and DML) is < 0.05 in both the groups, implying that there was significant improvement in both the groups for each of the assessed parameters.

Table 8: Inter-group comparison of Phalen's test time

Phalen's test time		Mean	Std. Deviation	<i>P value*</i>
At Baseline	Dexamethasone	33.73	8.304	
	Triamcinolone	35.50	8.687	0.390
After 2 months	Dexamethasone	51.45	5.154	
	Triamcinolone	52.81	4.845	0.266
After 4 months	Dexamethasone	42.88	3.806	
	Triamcinolone	43.22	4.817	0.745

*By Independent Samples t-test

Table 8 shows the intergroup comparison of mean Phalen's test time at baseline, after 2 months and after 4 months. The mean Baseline Phalen's test time in Dexamethasone group was 33.73 ± 8.304 seconds and of Triamcinolone group was 35.5 ± 8.687 seconds. The P value is > 0.05 and hence there is no significant difference between the two groups at baseline with respect to Phalen's test time. The mean Phalen's test time at the 2nd month in Dexamethasone group was 51.45 ± 5.154 seconds and of Triamcinolone group is 52.81 ± 4.845 seconds. The P value is > 0.05 and hence there is no significant difference between the two groups at 2nd month follow-up. The mean Phalen's test time at the 4th month in Dexamethasone group is 42.88 ± 3.806 seconds and of Triamcinolone group is 43.22 ± 4.817 seconds. The P value is > 0.05 and hence there is no significant difference between the two groups even at the 4th month follow-up.

Table 9: Inter-group comparison of Visual Analogue Scale score

VAS score		Mean	Std. Deviation	<i>P value</i>
At Baseline	Dexamethasone	6.36	0.994	
	Triamcinolone	6.17	0.910	<i>0.393</i>
After 2 months	Dexamethasone	1.85	0.870	
	Triamcinolone	1.39	1.225	<i>0.079</i>
After 4 months	Dexamethasone	2.06	1.116	
	Triamcinolone	1.75	1.422	<i>0.319</i>

Table 9 shows the intergroup comparison of mean VAS score at baseline (VAS0), after 2 months (VAS2) and after 4 months (VAS4). As is evident from the table, P value is > 0.05 at baseline, 2nd month and 4th months of follow-up which implies that there was no significant difference between the two groups in terms of the VAS score.

Table 10: Inter-group comparison of BCTQ score

BCTQ score		Mean	Std. Deviation	<i>P value</i>
At Baseline	Dexamethasone	49.18	17.747	
	Triamcinolone	51.81	17.139	<i>0.534</i>
After 2 months	Dexamethasone	21.15	3.043	
	Triamcinolone	22.78	6.551	<i>0.197</i>
After 4 months	Dexamethasone	21.61	4.723	
	Triamcinolone	23.83	7.193	<i>0.137</i>

Table 10 shows the intergroup comparison of mean BCTQ score at baseline (BCTQ0), after 2 months (BCTQ2) and after 4 months (BCTQ4). As is evident from the table, *P* value is > 0.05 at baseline, 2nd month and 4th months of follow-up which implies that there was no significant difference between the two groups in terms of the BCTQ score.

Table 11: Inter-group comparison of NCS parameters

NCV parameter	Group	Mean	Std. Deviation	<i>P</i> value
SNCV at baseline	Dexamethasone	37.380	6.2455	
	Triamcinolone	39.217	6.2764	<i>0.228</i>
SNCV after 4 months	Dexamethasone	44.394	6.7027	
	Triamcinolone	45.428	6.2912	<i>0.511</i>
DML at baseline	Dexamethasone	4.242	0.7150	
	Triamcinolone	4.244	1.1816	<i>0.995</i>
DML after 4 months	Dexamethasone	3.367	0.5605	
	Triamcinolone	3.300	1.0871	<i>0.753</i>

Table 11 shows the intergroup comparison of mean NCS parameters, namely the SNCV and DML at baseline, after 2 months and after 4 months. As is evident from the table, *P* value is > 0.05 at baseline, 2nd month and 4th months of follow-up which implies that there was no significant difference between the two groups in terms of the NCS parameters as well.

Table 12: Inter-group comparison of Post-procedure Pain duration:

	Mean (days)	Std. Deviation	<i>P value</i>
Dexamethasone	2.67	0.692	
Triamcinolone	5.31	1.037	0.048

Table 12 shows the inter-group comparison of post-procedure pain duration which was significantly more in the Triamcinolone group (mean duration of 5.31 ± 1.037 days) compared to Dexamethasone group (mean duration of 2.67 ± 0.692 days) with a $p\text{ value} < 0.05$.

DISCUSSION

DISCUSSION

Carpal tunnel syndrome is a very commonly encountered condition in our clinical setups. If left untreated, the initial sensory symptoms can progress to motor weakness of the hand causing difficulty in holding and gripping objects, increasing patient's dependence on others for their daily activities. Many patients report increased symptoms during night-time, disturbing their sleep, resulting in daytime sleepiness, difficulty and decreased efficiency in doing their activities of daily living, thereby decreasing the quality of life.

Similar to the disease prevalence as reported by Fischer et al, we found that CTS was much more common in females than in males (84% versus 16%).

Obesity is a well-recognized risk factor for development of CTS as mentioned by Genova et al. In our study, we found that 60% of the patients were found to be in the overweight category.

Our study was conducted in the Western State of Rajasthan where milking cows is a very common daily task in many households which, due to causing repetitive trauma to the wrist, is a primary factor predisposing this population to the development of CTS.

Local corticosteroid injections have been successfully used for the treatment of CTS for more than half a century and found to be effective for the same (27,28,55). Different authors like *Piazzini et al.*, *Peters-Veluthamaningal et al.*, *Ertem et al.*, *Marshall et al.* etc. had previously shown that local corticosteroid injection in CTS had good short-term efficacy to reduce the symptoms of CTS. In our study, we got similar results implying that steroids are indeed effective in reducing the symptoms of CTS.

So far in literature, there has been no specification regarding any particular corticosteroid to be used as the standard treatment in CTS. It has been noted that triamcinolone acetonide is currently one of the most commonly used steroid injection for treatment of CTS. But, similar to what was reported by *Mackinnon et al.*, that Triamcinolone due to its characteristics like being water-insoluble, white sediment

forming, and having the property of crystallization at the injection site, is more prone to develop more adverse events after local injection (29), we observed the same in our study as post-injection flare and injection site pain was significantly more in the Triamcinolone group compared to the Dexamethasone group. Mackinnon et al. had also reported that triamcinolone caused widespread axonal and myelin degeneration, and that if a physician accidentally injects triamcinolone acetone directly into the nerves, it could cause permanent nerve injury. However, since we performed all the injections under ultrasound guidance, we did not encounter any event of nerve injury in either group and so the propensity of more nerve damage with Triamcinolone cannot be commented based on our study.

Furthermore, as reported by *Habib GS et al.* and *Wang AA et al.* (56,57) that the use of local dexamethasone injection did not have any systemic side effects like changing the blood sugar level of the patients was also confirmed in our study as the blood sugar values of the patients who received Dexamethasone in our study remained in the normal range after the procedure.

There are not many studies on the efficacy of dexamethasone for the treatment of CTS. *Niempoog et al.* studied the efficacy of dexamethasone injection for the treatment of CTS in pregnancy and showed that it was an effective treatment option for controlling the symptoms of CTS in pregnant women (52). *Moghtaderi et al* also reported significant improvement in pain intensity and electrophysiological parameters after dexamethasone injection in pregnant women with CTS (53). However, due to ethical concerns, we have not included pregnant women in our study and they were managed conservatively without any injection.

Dilokhuttakarn et al in a prospective, randomized, double blind, controlled, clinical trial compared the efficacy of dexamethasone and triamcinolone injection in CTS and found that dexamethasone injection was effective and significantly improved the positive Phalen's test time compared to triamcinolone acetone but there was no significant difference between the two groups. Our study also got similar results with significant improvement in all the assessed parameters in both the groups but there wasn't any significant difference between the two groups in any assessed parameter.

CONCLUSION

CONCLUSION

- It is thus evident from our study that dexamethasone sodium phosphate injection is a safe and equally effective alternative to the commonly used triamcinolone acetonide injection in CTS, with the possibility of lesser complications.
- Using ultrasound guidance for performing the injection is recommended as it can avoid the potential complications like nerve injury, vascular injury and tendon injury, which can be caused by blind injection into the nerve.
- In addition to treating the symptoms, the predisposing factors need to be addressed properly, otherwise there will always remain recurrences of CTS even after the injection.

STRENGTHS:

Prior to recruitment for the study, all the clinically diagnosed cases were further confirmed by electrophysiological tests.

LIMITATIONS:

1. One limitation of the current study is less sample size. In our study recruitment period of 18 months, we could recruit only 69 patients though we had initially expected a lot more but the covid pandemic and the subsequent lockdown drastically affected the patient in-flow and thereby led to a reduction in the number of patients recruited.
2. It was an open labelled randomised control trial and no blinding was done.
3. We excluded the pregnant women with CTS from our study due to ethical concerns.
4. Another limitation of the study is a follow-up duration of only 4 months after the injection due to which the long-term efficacy of these steroids could not be assessed.

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ANNEXURES

ANNEXURE 1



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2052

Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/968

Project title: "Efficacy of dexamethasone versus triamcinolone injection in patients with carpal tunnel syndrome, a randomized control trial"

Nature of Project: Research Project
Submitted as: M.D. Dissertation
Student Name: Dr. Merrin Meria Mathew
Guide: Dr. Ravi Gaur
Co-Guide: Dr. Nitesh Gonnade & Dr. Pushpinder Khara

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Enclose:

1. Annexure 1


Dr. Praveen Sharma
Member Secretary
Institutional Ethics Committee
AIIMS, Jodhpur

Page 1 of 2

ANNEXURE 2
All India Institute of Medical Sciences, Jodhpur, Rajasthan
Informed Consent Form

Title of Thesis/Dissertation: EFFICACY OF DEXAMETHASONE VERSUS TRIAMCINOLONE INJECTION IN PATIENTS WITH CARPAL TUNNEL SYNDROME, A RANDOMIZED CONTROL TRIAL

Name of PG student: DR. MERRIN MERIA MATHEW
9495274900

Tel. No. 9745010051/

Patient/Volunteer Identification No.: _____

I, _____ S/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of this study, the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary, and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individuals from Department of Physical Medicine and Rehabilitation, AIIMS, Jodhpur or from regulatory authorities. I give permission to these individuals to have access to my records.

Date: _____

Place: _____
impression

Signature/Left thumb

This to certify that the above consent has been obtained in my presence.

Date: _____

Place: _____

Signature of PG student

1. Witness 1

2. Witness 2

Signature
Name: _____

Signature
Name: _____

Address: _____

Address: _____

ANNEXURE 3

अखिल भारतीय आयुर्विज्ञान संस्थान

जोधपुर, राजस्थान

सूचित सहमति पत्र

थीसिस का शीर्षक: कार्पल टनल सिंड्रोम के मरीजों में इंजेक्शन डेक्सामेथासोन और टायमसिनॉलोन के प्रभावों का तुलनात्मक अध्ययन।

पीजी छात्र का नाम : डॉ. मेरिन मेरिया मैथ्यू दूरभाष। संख्या 9745010051 / 9495274900

रोगी / स्वयंसेवी पहचान संख्या: _____

मैं, _____ पुत्र/पुत्री _____

निवासी _____ मेरी पूर्ण, निः शुल्क, स्वैच्छिक सहमति देता हु इस अध्ययन का हिस्सा बनने के लिए, जिसकी प्रक्रिया और प्रकृति मेरी पूरी संतुष्टि के लिए मेरी अपनी भाषा में मुझे समझाया गया है। मैं पुष्टि करता हूं कि मेरे पास प्रश्न पूछने का अवसर था।

मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और किसी भी कारण के बिना, किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार से अवगत हूं। मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड्स के बारे में एकत्र की गई जानकारी को चिकित्सा विभाग, एम्स जोधपुर से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन व्यक्तियों के लिए अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं। मुझ यह भी पता है कि अध्ययन के दौरान एकत्र किए गए नमूने को आगे के शोध में इस्तेमाल किया जा सकता है, और मैं इसके लिए अनुमति देता हूं।

दिनांक: _____

स्थान: _____

हस्ताक्षर/ बाएं अंगूठे की छाप

यह प्रमाणित करने के लिए कि उपर्युक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।

तारीख: _____

स्थान: _____

हस्ताक्षर पीजी छात्र

साक्षी 1

हस्ताक्षर

नाम: _____

स्थान: _____

साक्षी 2

हस्ताक्षर

नाम: _____

स्थान: _____

ANNEXURE 4

PATIENT INFORMATION SHEET

Name of the patient:

Patient ID.:

EFFICACY OF DEXAMETHASONE VERSUS TRIAMCINOLONE INJECTION IN PATIENTS WITH CARPAL TUNNEL SYNDROME, A RANDOMIZED CONTROL TRIAL

Aim of the study: To compare the efficacy of Dexamethasone and Triamcinolone injection in patients with carpal tunnel syndrome.

Study site: Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Jodhpur, Rajasthan.

Study procedure: You will be given a 4 ml injection of either Dexamethasone or Triamcinolone in your wrist as per standard ultrasound guided perineural injection protocol. This will relieve your symptoms. The improvement will be followed-up after 1 month, 2 months and 4 months.

Likely benefit: Study will help to understand whether Dexamethasone injection can be used as a good alternative to usual Triamcinolone injection which has some reported side effects. Dexamethasone is safe and provides the same and probably better improvement in your symptoms.

Confidentiality: All the data collected from each study participant will be kept highly confidential.

Risk: Enrollment in above study poses no substantial risk to any of the study participant and if any point of time participant wants to withdraw himself/ herself, he/ she can do so voluntarily at any point of time during the study.

For further information / questions, the following personnel can be contacted:

Dr. Merrin Meria Mathew,
Junior Resident, Department of Physical Medicine and Rehabilitation,
All India Institute of Medical Sciences, Jodhpur, Rajasthan.
Ph: 09745010051/09495274900

ANNEXURE 5

रोगी सूचना पत्र

रोगी का नाम

रोगी आईडी

कार्पल टनल सिंड्रोम के मरीजों पर इंजेक्शन डेक्सामेथासोन बनाम ट्रायमसिनॉलोन के प्रभावों का तुलनात्मक अध्ययन

- 1 अध्ययन का उद्देश्य— कार्पल टनल सिंड्रोम के मरीजों में इंजेक्शन डेक्सामेथासोन और ट्रायमसिनॉलोन के प्रभावों का तुलनात्मक अध्ययन।
2. अध्ययन का स्थान —शारीरिक चिकित्सा एवं पुनर्वास विभाग, अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान
3. अध्ययन प्रक्रिया— इसमें मरीज की कलाई में या तो इंजेक्शन डेक्सामेथासोन या ट्रायमसिनॉलोन की 4उस मात्रा ,मानक सोनोग्राफी तकनीकी सहायता से डाली जाएगी, जिससे लक्षणों में राहत या सुधार मिलेगी। सुधारों को देखने के लिए इंजेक्शन के बाद पहले , दूसरे ,व चौथे महीने पर मरीज को अस्पताल आना होगा ।
4. संभावित लाभ — यह अध्ययन यह पता लगाने में मदद करेगा कि इंजेक्शन डेक्सामेथासोन अधिकांश इस्तेमाल होने वाले इंजेक्शन ट्रायमसिनॉलोन का एक अच्छा विकल्प हो सकता है,ताकि ट्रियामेसिनोलन के दुष्प्रभावों से बचा जा सके। इंजेक्शन डेक्सामेथासोन का इस्तेमाल सुरक्षित है जिससे लक्षण में बेहतर सुधार होगा।
5. गोपनीयता— प्रत्येक प्रतिभागी जो अध्ययन में भाग ले रहा है उनसे प्राप्त सभी डाटा को अत्यधिक गोपनीय रखा जाएगा।
6. जोखिम— उपरोक्त अध्ययन में स्वैच्छिक नामांकित प्रतिभागी को कोई बड़ा जोखिम नहीं होता है और अध्ययन के दौरान कभी भी प्रतिभागी अपना नाम वापस ले सकता है।

अधिक जानकारी और प्रश्नों के लिए, निम्नलिखित कर्मों से संपर्क किया जा सकता है :

डॉ मेरिन मेरिया मैथ्यू

शारीरिक चिकित्सा और पुनर्वास विभाग,

अखिल भारतीय आयुर्विज्ञान संस्थान,

जोधपुर, राजस्थान

फोन नंबर—09745010051 / 09495274900

ANNEXURE 6

Date –

CASE RECORD FORM

EFFICACY OF DEXAMETHASONE VERSUS TRIAMCINOLONE INJECTION
IN PATIENTS WITH CARPAL TUNNEL SYNDROME, A RANDOMIZED
CONTROL TRIAL

Name- Age/Sex - BMI-

Hospital ID- AIIMS/JDH/ Occupation-

Address-

Contact no.-

Dominant hand-

Diagnosis-

Brief history-

Past medical or surgical history/ comorbidities-

O/E-

Phalen's test- Positive Phalen's test time- _____seconds

Tinel's test- RBS-

NCV findings-

SNCV- DSL- DML-

Amplitude (Sensory)- Amplitude (Motor)-

Group allotted-

Name of Procedure-

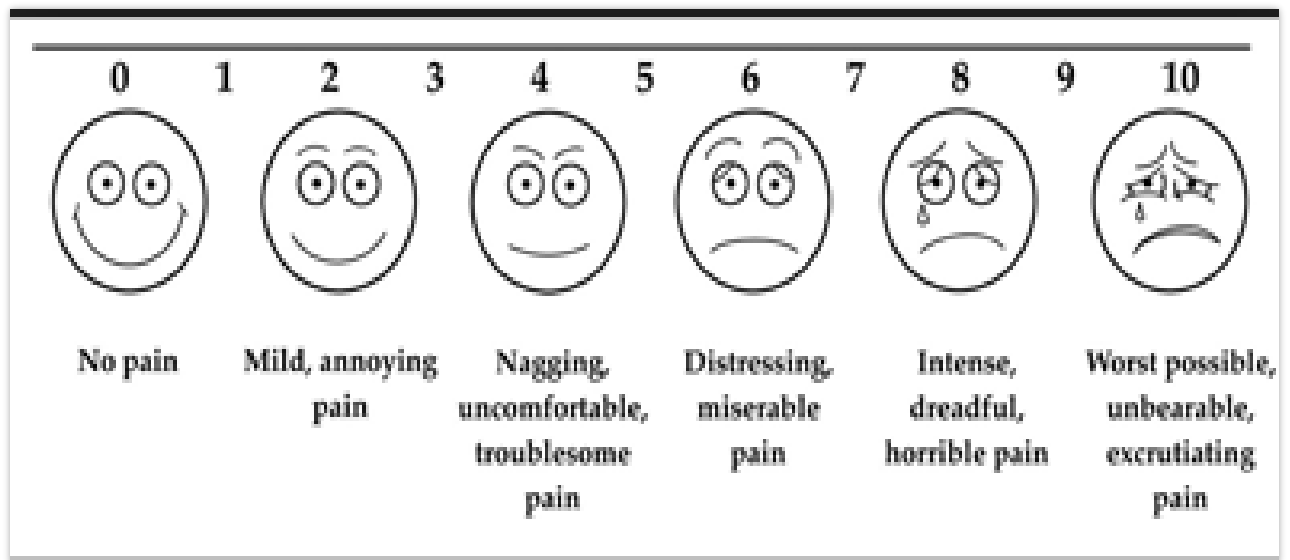
Any adverse events-

OUTCOMES:

OUTCOME	Pre-Treatment	After 2 months	After 4 months
Positive Phalen's Test Time (sec)			
VAS			
BCTQ total score			
BCTQs			
BCTQf			

	Pre-Treatment	After 4 months
NCS (SNCV)		
NCS (DSL)		
NCS (DML)		
Amplitude (Sensory)		
Amplitude (Motor)		

VISUAL ANALOG SCALE (VAS)



This Photo by Unknown Author is licensed under CCBY-SA

Boston Carpal Tunnel Syndrome Questionnaire (BCTQ)

(一) Symptom severity scale (11 items)

	1	2	3	4	5
1. How severe is the hand or wrist pain that you have at night?	Normal	Slight	Medium	Severe	Very serious
2. How often did hand or wrist pain wake you up during a typical night in the past two weeks?	Normal	Once	2 to 3 times	4 to 5 times	More than 5 times
3. Do you typically have pain in your hand or wrist during the daytime?	No pain	Slight	Medium	Severe	Very serious
4. How often do you have hand or wrist pain during daytime?	Normal	1-2 times / day	3-5 times / day	More than 5 times	Continued
5. How long on average does an episode of pain last during the daytime?	Normal	< 10minutes	10~60 Continued	> 60minutes	Continued
6. Do you have numbness (loss of sensation) in your hand?	Normal	Slight	Medium	Severe	Very serious
7. Do you have weakness in your hand or wrist?	Normal	Slight	Medium	Severe	Very serious
8. Do you have tingling sensations in your hand?	Normal	Slight	Medium	Severe	Very serious
9. How severe is numbness (loss of sensation) or tingling at night?	Normal	Slight	Medium	Severe	Very serious
10. How often did hand numbness or tingling wake you up during a typical night during the past two weeks?	Normal	Once	2 to 3 times	4 to 5 times	More than 5 times
11. Do you have difficulty with the grasping and use of small objects such as keys or pens?	Without difficulty	Little difficulty	Moderately difficulty	Very difficulty	Very difficult

(二) Functional status scale (8 items) :

	No difficulty	Little difficulty	Moderate difficulty	Intense difficulty	Cannot perform the activity at all due to hands and wrists symptoms
Writing	1	2	3	4	5
Buttoning of clothes	1	2	3	4	5
Holding a book while reading	1	2	3	4	5
Gripping of a telephone handle	1	2	3	4	5
Opening of jars	1	2	3	4	5
Household chores	1	2	3	4	5
Carrying of grocery basket	1	2	3	4	5
Bathing and dressing	1	2	3	4	5

MASTER CHART

MASTER CHART																																							
Name	Age	Gender	Occupation	Dominant hand	Diagnosis	Rand Group	BMI	Category	Uncont Diabetes	Hyper tension	Hypo thyroid	Wrist Injury	Smoking	Alco intake	RBS before Procedure	RBS after Procedure	Phalen Test	P0	P2	P4	Time Test	SVCV0	SVCV4	DMV4	DMV4	Severity	Value	VASA	BCIQ00	BCIQ02	BCIQ04	BCIQ06	BCIQ08	BCIQ10	BCIQ12	BCIQ14			
Madi Devi	49	Female	Manual worker	Right	Right Mild CTS	Triamcinolone	24.30	Normal	No	No	No	No	No	No	109	103	Positive	27	50	40	Positive	38.8	45.0	31	22	Mild	6	1											
Mamta Ma	28	Female	Housewife	Right	Right Mild CTS	Dexamethasone	23.50	Normal	No	No	No	No	No	No	92	95	Positive	27	55	45	Positive	47.2	51.1	40	32	Mild	7	2											
Lupia Devi	30	Female	Housewife	Right	Right Mild CTS	Dexamethasone	26.20	Overweight	No	No	No	No	No	No	100	97	Positive	25	42	34	Positive	26.5	30.5	41	33	Mild	7	1	1	32	12	12	24	8	8	5.6	20	20	
Sai Devi	38	Female	Manual worker	Right	Left Mild CTS	Dexamethasone	24.50	Normal	No	No	No	No	No	No	122	118	Positive	23	46	38	Negative	39.9	45.1	39	31	Mild	7	1	2	45	12	12	28	9	9	7.1	21	21	
Sugru L. Muni	30	Female	Manual worker	Right	Left Mild CTS	Triamcinolone	24.50	Normal	No	No	No	No	No	No	132	121	Positive	16	48	36	Positive	33.3	39.6	35	29	Mild	7	1	4	40	14	14	29	16	16	6.9	30	30	
Kamini	36	Female	Housewife	Right	Right Mild CTS	Triamcinolone	25.60	Overweight	No	No	No	No	No	No	114	120	Positive	25	58	41	Positive	39.1	45.7	41	33	Mild	7	1	4	45	22	22	28	16	16	7.1	38	40	
Kamini	36	Female	Housewife	Right	Left Moderate CTS	Triamcinolone	26.80	Overweight	No	No	No	No	No	No	97	95	Positive	23	59	38	Positive	46.6	53.5	44	32	Moderate	7	1	4	5	45	22	22	28	16	16	7.1	38	40
Sugru Kamani	55	Female	Manual worker	Right	Left Moderate CTS	Triamcinolone	27.20	Overweight	No	No	No	No	No	No	96	92	Positive	22	50	43	Positive	33.3	39.6	35	26	Moderate	7	1	4	2	41	11	11	13	9	9	5.4	20	20
Lupia Devi	41	Female	Housewife	Right	Right Moderate CTS	Dexamethasone	28.60	Overweight	No	No	No	No	No	No	116	112	Positive	21	45	40	Positive	39.2	46.8	45	38	Moderate	7	1	0	43	11	11	15	8	8	5.8	19	19	
Lupia	55	Female	Housewife	Right	Right Moderate CTS	Dexamethasone	28.60	Overweight	No	No	No	No	No	No	116	112	Positive	20	48	40	Positive	39.2	46.8	45	38	Moderate	7	1	3	44	22	22	27	10	11	7.1	32	33	
Lupia	43	Female	Manual worker	Right	Left Mild CTS	Triamcinolone	26.90	Overweight	No	No	No	No	No	No	128	125	Positive	35	51	39	Positive	39.5	48.6	34	26	Moderate	7	1	2	39	12	12	28	9	8	6.7	21	20	
Shetal panchanya	38	Female	Housewife	Right	Right Mild CTS	Dexamethasone	25.90	Overweight	No	No	No	No	No	No	132	125	Positive	30	43	40	Negative	40.1	47.5	32	25	Mild	6	1	2	44	11	11	27	10	8	7.1	21	19	
Kamini	28	Female	Housewife	Right	Right Moderate CTS	Triamcinolone	27.60	Overweight	No	No	No	No	No	No	89	93	Positive	30	43	40	Negative	40.1	47.5	32	25	Mild	6	1	2	39	11	11	28	8	9	6.7	19	20	
Sugru Kamani	55	Female	Housewife	Right	Right Moderate CTS	Triamcinolone	24.90	Normal	No	No	No	No	No	No	107	110	Positive	46	51	46	Positive	30.8	35.6	56	44	Moderate	6	1	1	27	11	11	29	12	8	5.6	23	19	
Sugru Kamani	45	Female	Other	Right	Right Mild CTS	Dexamethasone	28.60	Overweight	No	No	No	No	No	No	115	110	Positive	35	50	45	Negative	25.1	31.6	87	73	Moderate	5	1	4	39	20	22	27	16	16	6.6	36	38	
Sugru Kamani	45	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	24.60	Normal	No	No	No	No	No	No	93	97	Positive	36	45	42	Positive	41.3	46.4	41	32	Mild	5	1	4	34	22	22	34	16	18	6.8	18	40	
Nevamini Devi	55	Female	Housewife	Right	Left Moderate CTS	Triamcinolone	27.60	Overweight	No	No	No	No	No	No	106	110	Positive	42	57	44	Negative	26.1	32.4	74	64	Moderate	5	1	3	29	11	11	16	9	8	4.5	20	19	
Tulsi Devi	31	Female	Housewife	Right	Right Moderate CTS	Dexamethasone	17.90	Underweight	No	No	No	No	No	No	119	120	Positive	28	39	36	Positive	31.4	36.7	45	36	Moderate	6	1	4	36	20	22	28	16	16	6.4	36	38	
Kail Devi	45	Female	Manual worker	Right	Right Mild CTS	Triamcinolone	26.80	Overweight	No	No	No	No	No	No	106	102	Positive	38	52	48	Positive	26.5	32.6	48	39	Moderate	5	1	1	34	11	11	21	9	8	5.5	20	19	
Kail Devi	54	Female	Housewife	Right	Left Moderate CTS	Triamcinolone	29.80	Overweight	No	No	No	No	No	No	110	115	Positive	45	51	47	Positive	45.5	52.4	34	25	Mild	5	1	1	32	11	11	17	10	8	4.9	21	19	
Kail Devi	44	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	27.80	Overweight	No	No	No	No	No	No	88	92	Positive	32	56	44	Positive	29.9	54.1	44	37	Mild	5	1	0	31	11	11	13	8	8	6.4	19	19	
Kail Devi	44	Female	Housewife	Right	Left Moderate CTS	Triamcinolone	28.30	Overweight	No	No	No	No	No	No	107	110	Positive	40	56	45	Positive	36.6	43.5	42	34	Mild	7	1	3	34	11	11	20	12	8	5.4	23	19	
Baby Vishnoi	38	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	26.50	Overweight	No	No	No	No	No	No	113	118	Positive	43	58	43	Negative	35.0	35.8	46	37	Moderate	7	1	3	43	12	16	18	9	9	8.1	21	25	
Babita Vishnoi	38	Female	Housewife	Right	Right Moderate CTS	Triamcinolone	24.60	Normal	No	No	No	No	No	No	115	111	Positive	46	52	45	Negative	38.3	44.2	50	43	Moderate	7	1	4	30	12	12	25	10	8	5.5	22	20	
Vijaya	29	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	26.50	Overweight	No	No	No	No	No	No	125	119	Positive	21	48	42	Positive	24.2	30.7	56	42	Moderate	7	1	3	31	16	16	25	11	11	5.6	27	27	
Vijaya Kumari	29	Female	Housewife	Left	Right Moderate CTS	Dexamethasone	26.80	Overweight	No	No	No	No	No	No	128	130	Positive	28	50	43	Positive	39.1	46.7	44	32	Moderate	6	1	3	39	11	11	8	8	8	4.7	19	19	
Phula Devi	38	Female	Manual worker	Right	Left Moderate CTS	Dexamethasone	25.70	Overweight	No	No	No	No	No	No	117	122	Positive	26	48	38	Positive	30.4	36.4	35	26	Moderate	7	1	4	49	12	12	32	10	10	8.1	22	22	
Shanti devi	38	Female	Housewife	Right	Right Mild CTS	Dexamethasone	27.40	Overweight	No	No	No	No	No	No	125	121	Positive	35	55	44	Positive	40.4	38.6	23	21	Mild	3	1	4	49	12	12	32	10	10	8.1	22	22	
Manju Sharma	38	Female	Housewife	Right	Right Mild CTS	Triamcinolone	30.80	Obese	No	No	No	No	No	No	118	116	Positive	42	57	46	Positive	45.5	52.1	38	29	Mild	5	1	3	48	11	11	33	9	9	8.1	20	20	
Ramdevi	42	Male	Other	Right	Left Mild CTS	Triamcinolone	23.40	Normal	No	No	No	No	No	No	108	110	Positive	44	57	49	Positive	41.3	47.6	37	28	Mild	7	1	2	16	11	16	8	8	8	2.4	19	24	
Sayer Kamani	57	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	22.20	Normal	No	No	No	No	No	No	107	103	Positive	28	53	45	Positive	26.4	32.1	56	42	Moderate	6	1	2	29	11	11	12	9	9	4.1	20	20	
Bhaskari	59	Male	Manual worker	Right	Right Mild CTS	Dexamethasone	27.50	Overweight	No	No	No	No	No	No	110	118	Positive	46	57	45	Positive	39.0	45.3	39	28	Mild	5	1	1	15	11	11	8	8	8	2.3	19	19	
Shreeji Vaishnav	28	Male	Other	Right	Right Mild CTS	Dexamethasone	25.90	Overweight	No	No	No	No	No	No	112	110	Positive	43	55	43	Positive	48.3	53.4	37	27	Mild	6	1	3	15	11	11	22	8	8	8	23	19	30
Manisha Pareek	45	Female	Housewife	Left	Right Moderate CTS	Triamcinolone	25.60	Overweight	No	No	No	No	No	No	130	120	Positive	45	59	46	Positive	46.0	52.3	46	35	Moderate	7	1	0	19	11	11	8	8	8	2.7	19	19	
Deepa Choudhary	44	Female	Housewife	Right	Right Mild CTS	Triamcinolone	22.00	Normal	No	No	No	No	No	No	126	120	Positive	41	57	49	Positive	47.0	52.5	39	28	Mild	6	1	0	45	11	11	25	8	8	7.0	19	19	
Guddi devi	34	Female	Housewife	Right	Left Moderate CTS	Dexamethasone	26.03	Overweight	No	No	No	No	No	No	108	109	Positive	41	55	42	Positive	46.0	52.3	46	35	Moderate	7	1	1	14	11	11	8	8	8	2.2	19	19	
Rehana	27	Female	Other	Right	Left Moderate CTS	Triamcinolone	30.04	Obese	No	No	No	No	No	No	98	102	Positive	35	52	45	Positive	42.0	47.8	48	38	Moderate	7	1	2	36	11	11	36	8	8	7.2	19	19	
Kulvi Devi	56	Female	Housewife	Right	Left Mild CTS	Dexamethasone	25.63	Overweight	No	No	No	No	No	No	119	122	Positive	46	57	43	Positive	41.3	46.8	41	33	Mild	5	1	1	17	11	11	12	8	8	2.9	19	19	
Mona Kamani	46	Female	Manual worker	Right	Right Moderate CTS	Dexamethasone	27.05	Overweight	No	No	No	No	No	No	96	99	Positive	36	57	48	Positive	39.0	47.3	47	38	Moderate	7	1	2	13	14	16	8	8	8	2.1	22	24	
Shanti	45	Female	Housewife	Right	Right Mild CTS	Dexamethasone	21.46	Normal	No	No	No	No	No	No	102	109	Positive	38	54	42	Positive	44.0	50.2	40	31	Mild	6	1	0	43	11	11	20	8	8	6.3	19	19	
Bali Devi	43	Female	Housewife	Right	Left Moderate CTS	Triamcinolone	27.14	Overweight	No	No	No	No	No	No	105	110	Positive	29	50	43	Positive	42.0	48.2	49	28	Moderate	7	1	2	22	12	14	13	8	8	3.5	20	22	
Kama	52	Female	Housewife	Left	Right Moderate CTS	Triamcinolone	18.20	Underweight	No	No	No	No	No	No	117	120	Positive	37	52	40	Positive	39.2	45.3	47	36	Moderate	7	1	2	14	11	11	8	8	8	2.2	19	19	
Pappu Devi	48	Female	Manual worker	Right	Right Mild CTS	Triamcinolone	23.14	Normal	No	No	No	No	No	No	120	124	Positive	39	56	45	Positive	43.6	50.5	38	29	Mild	5	1	0	39	11	11	23	8	8	6.2	19	19	
Pama Ram	45	Male	Manual worker	Right	Left Moderate CTS	Dexamethasone	30.61	Obese	No	No	No	No	No	No	109	115	Positive	32	54	44	Positive	37.0	43.7	51	42	Moderate	7	1</											