Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the Effect of 5% Dextrose Water Injection with Corticosteroid Injection on Improving Clinical Signs and Performance of Patients with Mild to Moderate Cartilage Tunnel Syndrome in Patients Referring to Isfahan University of Medical Sciences Clinics during 2018: A Randomized Clinical Trial

Protocol summary

Study aim

The aim of this study was to assess the effect of 5% dextrose water injection compared to corticosteroid injection to improve clinical symptoms and performance of patients with mild to moderate carpal tunnel syndrome

Design

In this study, 36 patients with carpal tunnel syndrome (according to physician confirmation) were randomly divided into two equal groups and one group was treated with 5% Dextrose Water Injection and other group triamcinolone acetonide (corticosteroid.)

Settings and conduct

In this study, 36 patients with carpal tunnel syndrome (according to physician confirmation) referred to Alzahra hospital were randomly divided into two equal groups and one group was treated with 5% Dextrose Water Injection and other group triamcinolone acetonide (corticosteroid.)

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with mild to moderate carpal tunnel syndrome; patients with severe carpal tunnel syndrome. Exclusion criteria: patients with methemoglobinemia, favism and severe liver disease and thyroid disease; sensitization and allergy to local anesthetics; diseases that imitate symptoms of carpal tunnel syndrome such as cervical radiculopathy, peripheral neuropathy and trauma; corticosteroid injections and physiotherapy in the last three weeks; history of hand surgery in the last 6 months; having other neurological disorders.

Intervention groups

Group A: 5% Dextrose Water Injection Group B: triamcinolone acetonide (corticosteroid)

Main outcome variables

Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180209038673N4**
Registration date: **2019-05-16, 1398/02/26**
Registration timing: **retrospective**

Last update: **2019-05-16, 1398/02/26**
Update count: **0**

Registration date

2019-05-16, 1398/02/26

Registrant information

Name

Robab Sheikhpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date
2018-04-09, 1397/01/20
Actual recruitment end date
2019-03-20, 1397/12/29
Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison of the Effect of 5% Dextrose Water Injection with Corticosteroid Injection on Improving Clinical Signs and Performance of Patients with Mild to Moderate Cartilage Tunnel Syndrome in Patients Referring to Isfahan University of Medical Sciences Clinics during 2018: A Randomized Clinical Trial

Public title
Effect of 5% dextrose water injection compared to corticosteroid injection to improve clinical symptoms and performance of patients with mild to moderate carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate carpal tunnel syndrome
Exclusion criteria:
Patients with severe carpal tunnel syndrome Patients with methemoglobinemia, favism and severe liver disease and thyroid disease Sensitization and allergy to local anesthetics Diseases that imitate symptoms of carpal tunnel syndrome such as cervical radiculopathy, peripheral neuropathy and trauma Corticosteroid injections and physiotherapy in the last three weeks History of hand surgery in the last 6 months Having other neurological disorders
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
We divide each referral into two groups using a randomized table. This table is a collection of numbers. Consider numbers from 1 to 18 for intervention A and numbers 19 to 36 for B. Then let's move on one of the numbers and move in one of the preset directions and assign the numbers to one of the groups. Thus, patients are completely randomly divided.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients did not aware about prescription drugs (Dextrose Water and Corticosteroid)
Placebo
Not used
Assignment
Parallel
Other design features
In this study, 36 patients with carpal tunnel syndrome (according to physician confirmation) were randomly divided into two equal groups and one group was treated with 5% Dextrose Water Injection and other group corticosteroid.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2019-01-17, 1397/10/27
Ethics committee reference number
IR.MUI.MED.REC.1397.185

Health conditions studied

1

Description of health condition studied
Carpal tunnel syndrome
ICD-10 code
G56.0
ICD-10 code description
Carpal tunnel syndrome

Primary outcomes

1

Description
Severity of disease
Timepoint
Before treatment, 4 weeks and 12 weeks after treatment
Method of measurement
According to the questionnaire of 11 items of the severity of tunnel carpal syndrome

Secondary outcomes

1

Description
Severity of disease
Timepoint
Before treatment, 4 weeks and 12 weeks after treatment
Method of measurement
According to VAS scale

Intervention groups

1

Description
Intervention group A: Patients in this group were administered with acetaminophen (500 mg/ 6 hour during 2 weeks) and vitamin B6 (40 mg/daily) during 1 months. Then, patients were injected with Dextrose water 5% at a meeting.
Category
Placebo

2

Description
Intervention group B: Patients in this group were treated with acetaminophen (500 mg every 6 hours for 2 weeks) and vitamin B6 (40 mg / day) for 1 month. Then patients were injected with 1 cc triamcinolone acetonide (40 mg / ml diluted by 1 cc normal salin)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Safoura Aghaee
Street address
Isfahan University of Medical Science,Hezar Jareeb Street, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooi Javanmard
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Isfahan University of Medical Science,Hezar Jarib street, Isfahan
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saghaei826@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Safoura Aghaee
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Position

Resident

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Contact

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Full name of responsible person

Safoura

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data were collected from two groups of patients and may be available to physicians in the future.

When the data will become available and for how long

The next one years

To whom data/document is available

Physicians

Under which criteria data/document could be used

If physical medicine need the results, I present them

From where data/document is obtainable

E-mail

What processes are involved for a request to access data/document

One year later via E-mail

Comments

I have not explannation