Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of ultrasound-guided local corticosteroid injection with dextrose 5% solution injection in carpal tunnel syndrome.

Protocol summary

Study aim
Comparison of the effectiveness of local corticosteroid injection with injection of dextrose 5% solution in patients with carpal tunnel syndrome.

Design
Double blinded randomized control trial.

Settings and conduct
This study will be conducted on physical medicine and rehabilitation department of Rasool Akram hospital, Tehran, Iran. Patients with mild to moderate carpal tunnel syndrome (based on electrodiagnostic study) will be included in the study. Patients will be categorized into one of the following groups, using block randomization method: A Group: Will receive ultrasound-guided injection of 1CC triamcinolone into carpal tunnel. B Group: Will receive ultrasound-guided injection of 5 CC dextrose 5% into carpal tunnel. Patients in the both groups will receive the conservative treatments for carpal tunnel syndrome including wrist splints for six weeks as well. Patients will be followed after 2 weeks, one month and 6 months after injections. The pain intensity (Visual analogue scale) and the electrodiagnostic parameters are the main outcomes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Clinical diagnosis of carpal tunnel syndrome based on history (paresthesia over the distribution of median nerve) and possitive Tinnel and Phalen's tests. 2- Mild to moderate severity based on electrodiagnostic study. 3- Age between 18-65 years. exclusion criteria: Severe CTS, thenar atrophy, contraindication for injection, previous treatment , Neoplasm or trauma,tenderness and fracture of wrist, cervical radiculopathy, polyneuropathy.

Intervention groups
A Group: Ultrasound-guided injection of 1CC triamcinolone into carpal tunnel. B Group: Ultrasound-guided injection of 5 CC dextrose 5% into carpal tunnel.

Main outcome variables
Pain intensity (Visual analogue scale) and the electrodiagnostic parameters.

General information

Reason for update
A few days before 2019-12-10, I had requested for expected recruitment date to be on 2019-12-10. but unfortunately my request was accepted two days later and now the chief editor wants to know if I started my clinical trial 2 days sooner! but I didn`t. I started it exactly on 2019-12-12 after getting confirmation. the reason was busy schedule of the person who confirmed the registration on 12th . I forgot to write down the achieved date of starting my clinical trial and now I want to update that. thanks

Acronym
CTS

IRCT registration information
IRCT registration number: **IRCT20180603039969N1**
Registration date: **2019-12-12, 1398/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-13, 1399/04/23**
Update count: **1**

Registration date
2019-12-12, 1398/09/21

Registrant information

Name
Sara Moradnia
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Iran (Islamic Republic of)
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+98 61 3553 1210
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-10, 1398/09/19
Expected recruitment end date
2020-01-09, 1398/10/19
Actual recruitment start date
2019-12-12, 1398/09/21
Actual recruitment end date
2019-12-18, 1398/09/27
Trial completion date
2020-06-18, 1399/03/29

Scientific title
Comparison of the effectiveness of ultrasound-guided local corticosteroid injection with dextrose 5% solution injection in carpal tunnel syndrome.

Public title
Comparison of effectiveness of corticosteroid with dextrose in treatment of carpal tunnel syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with clinical diagnosis of carpal tunnel syndrome (paresthesia over the median nerve territory in the hand). Mild to moderate severity of carpal tunnel syndrome, based on electrodiagnostic studies. Age between 18-65 years,
Exclusion criteria:
Severe CTS (based on electrodiagnostic data). Signs of thenar atrophy. Contraindication for injection (such as history of hypersensitivity to corticosteroid, signs of local infection, immune deficiency, needle phobia. Diseases that mimic symptoms of carpal tunnel syndrome such as polyneuropathy, radiculopathy, and thoracic outlet syndrome. Surgical treatment or local injection in the last six months. Neoplastic or traumatic origin. Tenderness and fracture of wrist bones.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**
Actual sample size reached: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be categorized into one of the following groups, using block randomization method: Group A) Will receive ultrasound-guided injection of 1 ml triamcinolone (40 mg) into the carpal tunnel. Group B) Will receive ultrasound-guided injection of 5 ml dextrose 5% into the carpal tunnel.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the investigator are kept blinded. The injecting syringe is covered with sterile gas. Therefore, the investigator will be kept blinded to the type of injecting solution. Furthermore, the patient will be kept blinded to the type of injecting solution.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences.
Street address
Ethics committee, medical school, Iran University of Medical Sciences, Hemmat highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-11-20, 1397/08/29
Ethics committee reference number
IR.IUMS.FMD.REC.1397.216

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
Pain intensity (Visual analogue scale)
Timepoint
Baseline, and after 2 weeks, one month and 6 months after injection.
Method of measurement
10 point VAS scale.

2

Description
Electrodiagnosis parameters
Timepoint
Baseline, and after 2 weeks, one month and 6 months after injection.
Method of measurement
Electrodiagnostic study machine

Secondary outcomes

empty

Intervention groups

1

Description
One session of ultrasound-guided 1 CC Triamcinolone (Exir co, Tehran, Iran) injection into the carpal tunnel.
Category
Treatment - Drugs

2

Description
One session of ultrasound-guided 5 CC dextrose 5% solution (Ghazi co, Tehran, Iran) injection into the carpal tunnel.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-akram hospital
Full name of responsible person
Dr. Arash Babaei-Ghazani
Street address
Phsical medicine department- Rasoul-akram hospital- Niayesh street- Satarkhan Ave- Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. seyed Abbas Motevalian
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http://vcr.iums.ac.ir/page/3340/%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%AA-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
80
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Sara moradnia
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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moradnia.s@ajums.ac.ir
Web page address
http://hrmc.iums.ac.ir/

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data can be shared after making patients anonymous.
When the data will become available and for how long
Starting 6 months after publication.
To whom data/document is available
Data will be available for researchers on the internet.
Under which criteria data/document could be used
Data will be shared based on the request of the researchers.
From where data/document is obtainable
Dr. Babaei, Physical medicine department, Rasoul-akram hospital, Satarkhan Street, Tehran, Iran.
What processes are involved for a request to access data/document
Data will be sent via Email.
Comments