Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparative effectiveness of ultra-sound guided injections of corticosteroid and perineural dextrose 5% on clinical appearance, function, sonographic and electrodiagnostic findings in patients with cubital tunnel syndrome, a clinical trial study

Protocol summary

Study aim

Compare the effectiveness of ultra-sound guided injections of corticosteroid and perineural dextrose 5% on clinical appearance, function, sonographic and electrodiagnostic findings in patients with cubital tunnel syndrome

Design

The research is a randomized double blind clinical trial on 22 patients.

Settings and conduct

Samples are selected from patients with mild to moderate ulnar neuropathy referred to physical medicine and rehabilitation clinics under supervision of shiraz university of medical sciences divided into two groups. Block Randomization Assignment and Double blind methods are used. After obtaining informed consent, In group A corticosteroid is injected under guide of ultrasound and in group B ultrasound guided prineural injection of dextrose 5% is done. Finally effects on clinical appearance, function, sonographic and electrodiagnostic findings are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with age ranged from 20-65 years with diagnosis of mild to moderate ulnar neuropathy. The symptoms and signs persisted for at least 1 month. Exclusion criteria: Patients who are in a severe condition (paresis and muscle atrophy) and have brachial plexus neuropathy, history of elbow trauma or operation, rheumatologic disorder, peripheral neuropathy such as diabetes, previous perineural injection, malignancy, coagulopathy, pregnancy, active infection, or infection of injection site.

Intervention groups

Group A will receive locally 1 ml Methyl Prednisolone Acetate 40 mg and 1 ml Normal saline plus 1 ml Lidocaine 2%, under guide of ultrasound, in the cubital tunnel. Group B will receive locally 2 ml D5W plus 1 ml Lidocaine 2% ,under guide of ultrasound, in cubital tunnel.

Main outcome variables

Pain, Sensory and motor symptoms, Activity of daily living, Cross sectional area of ulnar nerve

General information

Reason for update

There was an error in recording the date of sample collection and in calculating the dates for patient examinations and preparing the necessary conditions to start the work. The correct dates for the intervention and sampling occurred after registration in the IRCT.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220929056056N1**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **prospective**

Last update: **2025-01-19, 1403/10/30**
Update count: **1**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

Maryam Mirhadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3845 4686

Email address

maryam.mirhadii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-08-21, 1402/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effectiveness of ultra-sound guided injections of corticosteroid and perineural dextrose 5% on clinical appearance, function, sonographic and electrodiagnostic findings in patients with cubital tunnel syndrome, a clinical trial study

Public title
Comparative effectiveness of ultra-sound guided injections of corticosteroid and perineural dextrose 5% in patients with cubital tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mild to moderate ulnar nerve entrapment Age of 20-65 years At least 1 month persistence of symptoms and signs

Exclusion criteria:
Severe condition Brachial plexus neuropathy History of elbow trauma or operation Rheumatologic disorder Peripheral neuropathy Previous perineural injection Malignancy Coagulopathy Pregnancy Active infection or infection of injection site

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly allocated in to two groups by Block Randomization Assignment and Double blind methods. We will have two lists of 11 patients, including the two intervention and control groups, at random. For concealment, method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by a person unaware of the division of groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: in this study, we does not have the ability to blind the participant because the participant is aware of receiving each intervention. Clinical care giver: we teach the caregiver how to complete the questionnaire. This person is not aware of receiving patient’s intervention. Researcher: this study does not have the ability to blind the researcher due to performing both interventions by himself and being aware of receiving the kind of intervention in each group. The outcome assessor of the complete questionnaires is given to a person who is not aware of the intervention performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Data analyzer: questionnaire are finally given to a person to review the information. This person does not know any of the steps of the work and the way of classification in which the intervention performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
No 5, Yas building, 6 Alley, Ahmad Abad Square, Farhangian Town

City
Shiraz

Province
Fars

Postal code
7179871123

Approval date
2022-09-19, 1401/06/28

Ethics committee reference number
IR.SUMS.MED.REC.1401.318

Health conditions studied

1

Description of health condition studied
Cubital tunnel syndrome

ICD-10 code
G56.20

ICD-10 code description
Lesion of ulnar nerve, unspecified upper limb

Primary outcomes

1

Description
Upper limb pain
Timepoint
Before intervention, three weeks and twelve weeks later
Method of measurement
Visual Analogue Scale, PRUNE questionnaire

2

Description
Sensory and Motor symptoms
Timepoint
Before intervention, three weeks and twelve weeks later
Method of measurement
PRUNE questionnaire

Secondary outcomes

1

Description
Function of patient
Timepoint
Before intervention, three weeks and twelve weeks later
Method of measurement
PRUNE questionnaire

2

Description
cross-sectional area of ulnar nerve
Timepoint
Before intervention and twelve weeks later
Method of measurement
Ultrasonography

Intervention groups

1

Description
First Intervention group: The patients will be placed in a supine position with the shoulder abducted and the elbow flexed at 90°.The ulnar nerve within the cubital tunnel will be identified in transverse plane, and the injection will be conducted after aseptic preparation. Patients will receive locally 1 ml Methyl Prednisolone Acetate 40 mg and 1 ml Normal saline plus 1 ml Lidocaine 2%, in one session. The patients have to complete the Visual Analog Scale and PRUNE questionnaires before entering the study and 3 and 12 weeks after intervention. Electrodiagnostic and sonographic findings will be evaluated before intervention and 12 weeks later.
Category
Rehabilitation

2

Description
Second Intervention group: The patients will be placed in a supine position with the shoulder abducted and the elbow flexed at 90°.The ulnar nerve within the cubital tunnel will be identified in transverse plane, and the injection will be conducted after aseptic preparation. Patients will receive locally 2 ml D5W plus 1 ml Lidocaine 2%, in one session. The patients have to complete the Visual Analog Scale and PRUNE questionnaires before entering the study and 3 and 12 weeks after intervention. Electrodiagnostic and sonographic findings will be evaluated before intervention and 12 weeks later.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza rehabilitation clinic
Full name of responsible person
Mani Ramzi
Street address
Namazi square
City
Shiraz
Province
Fars
Postal code
714737-71348
Phone
+98 71 3212 7700
Email
motahari@sums.ac.ir

2

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Amir Reza Mesbahi
Street address
Chamran Blvd, near to Niayesh Boulevard
City
Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Email
Rajaeehospital@sums.ac.ir

3

Recruitment center
Name of recruitment center

Shahid Faghihi Hospital
Full name of responsible person
Amir Reza Dehghanian
Street address
Zand St
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Email
FaghihiHsp@Sums.ac.ir

4

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Babak Hosseini
Street address
Chamran Blvd
City
Shiraz
Province
Fars
Postal code
7194634786
Phone
+98 71 3647 9531
Email
Hafez@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Front of Maaref school; Khalili Avenue
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3628 1506
Email
Info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Mirhadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No 5, Yas building, 6 Alley, Ahmad Abad Square, Farhangian Town
City
Shiraz
Province
Fars
Postal code
7179871123
Phone
+98 71 3845 4837
Email
maryam.mirhadii@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Mirhadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No 5, Yas building, 6 Alley, Ahmad Abad Square, Farhangian Town
City
Shiraz
Province
Fars

Postal code
7179871123
Phone
+98 71 3845 4837
Email
maryam.mirhadii@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Mirhadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No 5, Yas building, 6 Alley, Ahmad Abad Square, Farhangian Town
City
Shiraz
Province
Fars
Postal code
7179871123
Phone
+98 71 3845 4837
Email
maryam.mirhadii@gmail.com

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 available data can be shared after making people unidentifiable.
When the data will become available and for how long
Start access period one year after publishing the results.
To whom data/document is available
Everyone can access to this information.
Under which criteria data/document could be used
If the information in this study helps to improve the science process.
From where data/document is obtainable
Dr. Maryam Mirhadi, 00989177398937, maryam.mirhadii@gmail.com
What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted.
Comments