

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A comparison between corticosteroid injection versus local anaesthetic in treatment of lateral epicondylitis

Protocol summary

Summary

1) objectives: A comparison between corticosteroid injection versus local anaesthetic in treatment of lateral epicondylitis. 2) Design: Randomized clinical trial. 3) Setting and conduct: Group A will receive Corticosteroid injection (Methyl-prednisolon acetate 1 ml) single dose into the painful zone, Group B will receive a local anesthesia (procaine 2% 1 ml). VAS and Quick DASH questionnaires will be completed at the baseline, and then 3, 6, 12 weeks after treatment. Also, each patient will fill demographic questionnaire including age, gender, first referral time, involved hand, dominant hand and characteristic of disease. 4) Inclusion criteria: chronic pain in lateral zone of elbow, definite tenderness in lateral epicondylitis, age more than 15 years, and VAS score more than 6. exclusion criteria: radicular pain to the upper limbs, established Carpal Tunnel Syndrome, and past history of tennis elbow treatment. 5) Intervention: Group A will receive Corticosteroid injection (Methyl-prednisolon acetate 1 ml) single dose into the painful zone, Group B will receive a local anesthesia (procaine 2% 1 ml). 6) Main outcome measures: primary outcome is Survey of the elbow disability level measured with DASH questionnaire and secondary outcome is pain score that measured with VAS questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205127274N4**
Registration date: **2012-05-30, 1391/03/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 1470

Email address

mardani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-23, 1391/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between corticosteroid injection versus local anaesthetic in treatment of lateral epicondylitis

Public title

A comparison between corticosteroid injection versus local anaesthetic in treatment of elbow tendinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic pain in lateral zone of elbow; definite tenderness in lateral epicondylitis; age more than 15 years and VAS score more than 6. Exclusion

criteria: radicular pain to the upper limbs; established Carpal Tunnel Syndrome and past history of tennis elbow treatment.

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Science

Street address

Vice Chancellor for Research, Guilan University of
Medical Sciences, Namjou Avenue

City

Rasht

Postal code**Approval date**

2012-04-17, 1391/01/29

Ethics committee reference number

1910051505

Health conditions studied**1****Description of health condition studied**

Lateral epicondylitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Disability of elbow score

Timepoint

At baseline, and 3, 6, 12 weeks after treatment

Method of measurement

The Disabilities of the Arm, Shoulder and Hand
Score(QuickDash)

Secondary outcomes**1****Description**

Pain severity

Timepoint

At baseline, and 3, 6, 12 weeks after treatment

Method of measurement

Value-added service (VAS) score

Intervention groups**1****Description**

Group 2: Corticosteroid (Methyl-prednisolon acetate 1
ml) injection single dose into the painful zone

Category

Treatment - Drugs

2**Description**

Group 1: injection of a local anesthesia (procaine 2% 1
ml)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam-Reza Clinic of Poursina Hospital

Full name of responsible person

Dr Mohsen Mardani Kivi

Street address

Imam-Reza Clinic, Poursina Hospital, Parastar Avenue

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Guilan University of
Medical Sciences

Full name of responsible person

Dr. Abdolrasoul Sobhani, Research Chancellor of
Guilan University of Medical Science

Street address

Vice Chancellor for Research, Guilan University of
Medical Sciences, Namjou Avenue

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Guilan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Guilan University of Medical Science

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Orthopedic Department, Poursina Hospital, Parastar
Avenue.

City

Rasht

Postal code**Phone**

+98 13 1321 1470

Fax**Email**

dr_mohsen_mardani@yahoo.com

Web page address**Person responsible for scientific
inquiries****Contact****Name of organization / entity**

Guilan University of Medical Science

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Orthopedic Department, Poursina Hospital, Parastar
avenue.

City

Rasht

Postal code**Phone**

+98 13 1321 1470

Fax**Email**

dr_mohsen_mardani@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Orthopedic Surgeon, Assistant Professor

Other areas of specialty/work**Street address**

Orthopedic Department, Poursina Hospital, Parastar
Avenue

City

Rasht

Postal code**Phone**

00

Fax**Email**

dr_mohsen_mardani@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty