Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of Mesotherapy and Dry Needling in pain reduction and functional improvement in patients with Lateral Epicondylitis (Tennis Elbow): A Randomized clinical trial conducted at the physical medicine and rehabilitation clinics of Isfahan university of medical sciences.

Protocol summary

Study aim
The aim of this study is to compare the effects of dry needling and mesotherapy on pain intensity and function in patients with lateral epicondylitis (tennis elbow).

Design
This study is a randomized, parallel-group, open-label clinical trial. Participant allocation is performed using fixed-block randomization via the NCI's Clinical Trial Randomization Tool.

Settings and conduct
The study is being conducted at hospitals affiliated with Isfahan University of Medical Sciences. Sampling will be performed using a convenience sampling method based on specific criteria. Assessments will be carried out prior to the intervention, immediately after the completion of treatment, and eight weeks after the intervention concludes.

Participants/Inclusion and exclusion criteria
Fifty-eight patients with tennis elbow who meet the inclusion criteria will be enrolled in the study. Inclusion criteria comprise a diagnosis of lateral epicondylitis, age and eligibility requirements for participation, and informed consent. Patients with significant underlying conditions, concomitant upper-extremity injuries, or an inability to cooperate or attend follow-up visits will be excluded from the study.

Intervention groups
Participants are divided into two groups: the first group receives dry needling treatment, and the second group receives mesotherapy. The interventions will be performed by the researcher.

Main outcome variables
Pain intensity will be assessed using the VAS scale, while function and the level of disability will be evaluated using the PRTEE questionnaire.

General information

Reason for update

Acronym
MEDTEN Trial

IRCT registration information
IRCT registration number: **IRCT20260707070092N1**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information

Name
Fatemeh Abasi rad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-22, 1405/04/31

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Mesotherapy and Dry Needling in pain reduction and functional improvement in patients with Lateral Epicondylitis (Tennis Elbow): A Randomized clinical trial conducted at the physical medicine and rehabilitation clinics of Isfahan university of medical sciences.

Public title
Comparison of the effects of Mesotherapy and Dry Needling on pain reduction and functional improvement in patients with Tennis Elbow
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18–70 years pain at the lateral epicondyle for at least one month Pain during at least one of the following tests: Maudsley's test, Cozen 's test (resisted extension of the middle finger), or Mill's test.
Exclusion criteria:
Cervical radiculopathy Neuropathy Arthritis or a history of arthritis in the upper extremity Pregnancy History of forearm or elbow surgery Acute elbow trauma Autoimmune disease Local or systemic upper-extremity infection Fibromyalgia syndrome Cubital tunnel syndrome Carpal tunnel syndrome Ipsilateral medial epicondylitis Old fracture in the affected arm Elbow deformity Presence of coagulation disorders General contraindications for mesotherapy (exclusion criteria to be considered for patients undergoing the procedure): bleeding disorders; active infections in the treatment area (such as open wounds, skin infections, or severe acne); autoimmune diseases (e.g., lupus or rheumatoid arthritis); use of blood-thinning medications; and chronic skin conditions (such as psoriasis, eczema, or rosacea).
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to treatment groups using a fixed-block randomization method. Each block will consist of four patients, with assignment to the two treatment groups occurring at a 1:1 ratio. The randomization sequence will be generated using the Clinical Trial Randomization Tool provided by the National Cancer Institute (NCI). The randomization list will be kept confidential, and treatment group assignments will be made based on the order of patient enrollment in the study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences.
Street address
No.305,Kasra Building 7, C2 Neighborhood, Motahari Bolevard, Fooladshahr, Isfahan
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Approval date
2026-06-20, 1405/03/30
Ethics committee reference number
IR.MUI.MED.REC.1405.122

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis(Tennis elbow)
ICD-10 code
M77.1
ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Severity of pain associated with lateral epicondylitis (tennis elbow) in the study participants.
Timepoint
Before the start of the study, Immediately after completion of the study,8 weeks after completion of the study
Method of measurement

Pain severity will be assessed using the Visual Analog Scale (VAS)

2

Description
Functional status and limitations in performing activities related to the upper extremity in patients with lateral epicondylitis(tennis elbow)
Timepoint
Before the start of the study, Immediately after completion of the study,8 weeks after completion of the study
Method of measurement
Patient-Rated Tennis Elbow Evaluation (PRTEE)

Secondary outcomes

empty

Intervention groups

1

Description
The study involves 58 patients randomly assigned to either the mesotherapy group or the dry needling group. In the mesotherapy intervention group, 1 cc of Piroxicam (20 mg/1 ml; Caspian Tamin Pharmaceutical Company) is administered subcutaneously using a 27-gauge needle at a 45-degree angle; a volume of 0.5 cc is injected into each of two tender points—to reduce inflammation and alleviate pain—twice weekly for a period of three weeks.
Category
Treatment - Drugs

2

Description
Second Intervention Group (Dry Needling Group): Patients in this group receive dry needling twice weekly combined with exercise therapy. The dry needling procedure involves using a 0.25 × 0.25 mm needle at the point of maximal tenderness over the lateral epicondyle; the "Hong fast-in-fast-out" technique is applied, consisting of 20 rapid insertions and withdrawals at the designated site over a 20-second period. Additionally, the Chou technique—involving simultaneous rotation during needle insertion and withdrawal—is employed to facilitate needle movement.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
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Position
Medical resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available