Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Ultrasonographic Assessment of Pulsed Electromagnetic Field Stimulation (PEMFS) Effect on Tendon thickness in Tennis Elbow

Protocol summary

Study aim
Determining effect of adding Pulsed Electromagnetic field stimulation to routine physiotherapy on Common extensor tendon thickness, pain and disability in Tennis elbow patients

Design
clinical trial with a control group, with parallel groups, Single-blind, randomized, permuted block randomization was used for randomization

Settings and conduct
Tennis elbow patients enter the study voluntarily in Semnan University of Medical Sciences, will be randomly divided into two groups of control and intervention; Common Extensor Tendon (CET) thickness, pain and disability will be measured. intervention group receives 10 sessions including routine physiotherapy and Pulsed Electromagnetic Field Stimulation (PEMFS), control group receives 10 sessions including routine physiotherapy and sham PEMFS. After 10 session CET thickness, pain and disability of patients will be measured and compared

Participants/Inclusion and exclusion criteria
18-45 years tennis elbow patients with lateral elbow and forearm pain more than 6 weeks, tenderness in the origin of Extensor carpi radialis brevis, increased tenderness of dorsiflexion of wrist against resistance and of forearm supination will be included in the study. people with accompanying painful conditions, which may confuse the clinical picture such as upper extremity fracture, inflammatory arthritic conditions, carpal tunnel syndrome, thoracic outlet syndrome, cervical radiculopathy, and tendon ruptures or accompanying medial epicondylitis and people who has contraindications for Pulsed electromagnetic field stimulation such as tuberculosis, pregnancy, cardiac pacemaker, and malignancy will be excluded

Intervention groups
1)Active group: 10 sessions of routine physiotherapy and Electromagnetic Field Stimulation (PEMFS), 2) Control group: 10 sessions of routine physiotherapy and Sham PEMFS

Main outcome variables
Common Extensor Tendon thickness, pain, disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160808029264N14**
Registration date: **2022-01-16, 1400/10/26**
Registration timing: **prospective**

Last update: **2022-01-16, 1400/10/26**
Update count: **0**

Registration date
2022-01-16, 1400/10/26

Registrant information

Name
Rasool Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3344 1022

Email address
rasool.bagheri@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ultrasonographic Assessment of Pulsed Electromagnetic Field Stimulation (PEMFS) Effect on Tendon thickness in Tennis Elbow

Public title

The Effect of Magnet on Tendon thickness in Tennis Elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

lateral elbow and forearm pain that lasted for more than 6 weeks tenderness in the origin of the extensor carpi radialis brevis muscle increased tenderness of dorsiflexion of the wrist against resistance and of forearm supination Differential diagnosisfrom cervical problems and radial tunnel syndrome age between 18 - 45 years

Exclusion criteria:

accompanying painful conditions, which may confuse the clinical picture such as upper extremity fracture, inflammatory arthritic conditions, carpal tunnel syndrome, thoracic outlet syndrome, cervical radiculopathy, and tendon ruptures accompanying medial epicondylitis contraindications for Pulsed Electromagnetic Field Stimulation such as tuberculosis, pregnancy, cardiac pacemaker, and malignancy

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization: 4 blocks are used for randomization. The intervention groups are called A and the control group is called B. Different 4 blocks including A, B are defined in different permutations. We will have 15 blocks of 4. Each block is assigned a number from 1 to 6. Using a random number generator, the blocks are selected from 6 selected blocks, respectively. Eligible individuals are assigned to either A or B in each block (from left to right) in a predetermined order.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will not be aware of their group in control group ,sham Pulsed Electromagnetic Field Stimulation will be used Their elbows going to be positioned the same way as with the Group 1 patients in the same applicator. However, the electric current producer will be connected to another solenoid applicator (small solenoid). The patient will sense the same visual and auditory stimuli like the patient taking the active therapy, but no exposure to the real magnetic field

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comitee of Semnan University of Medical Sciences

Street address

Basij Blvd., Semnan., Semnan Province

City

Semnan

Province

Semnan

Postal code

99951-35198

Approval date

2021-12-29, 1400/10/08

Ethics committee reference number

IR.SEMUMS.REC.1400.240

Health conditions studied

1

Description of health condition studied

Tennis Elbow

ICD-10 code

M77.10

ICD-10 code description

Lateral epicondylitis, unspecified elbow

Primary outcomes

1

Description

Tendon thickness

Timepoint

The first session, last session

Method of measurement

Ultrasound device

Secondary outcomes

1

Description
Pain
Timepoint
The first session, last session
Method of measurement
Visual Analogue Scale

2

Description
Disability
Timepoint
The first session, last session
Method of measurement
Persian version of Patient-Rated Tennis Elbow Evaluation (PRTEE) Questionnaire

3

Description
Range of Motion
Timepoint
The first session, last session
Method of measurement
Goniometry

Intervention groups

1

Description
Intervention group: 10 session of physiotherapy, three sessions per week, each session consist of below: 1)Pulsed electromagnetic field stimulation (PEMFS) : The injured elbow of each patient will be put in the middle portion of a big circle solenoid applicator in prone position. The dose and application time will be selected according to the recommendations of the manufacturer. The total dose application is 6 mT/session. This dose is going to be completed by applying the PEMF in a frequency of 25 Hz and a frequency of 4.6 Hz, consecutively. A therapy session lasting for 30 min. 2)routine physiotherapy: Transcutaneous electrical nerve stimulation (TENS) , Low frequency TENS: 5 KHz modulated by 2 Hz frequency mode on acupuncture points , Infrared (IR) for 12 minutes on lateral aspect of elbow. Stretching , The Proprioceptive neuromuscular facilitation (PNF) stretching model was used with contraction for 10 seconds, short relaxation and then stretching for 15- 20 seconds of the forearm extensors (and the antagonist flexors subsequently), to be performed feeling the tightness, but below the pain threshold. Eccentric exercise: patient sitting on a chair, support the forearm on the armrest or on an adjacent table in prone position. The eccentric exercise is to lower the weight by flexing the wrist of the affected arm downwards and to lift it back again with the unaffected arm in three sets of 15 repetitions, in total 45 weight lowering manoeuvres. Ultrasound therapy: continuous ultrasonic waves of 1.5 MHz frequency and 1 W/cm2 power. The patients in the sitting position, and an acoustic gel containing no pharmacological active substance will be applied. Ultrasound will be applied to the lateral epicondyle in circular movements
Category
Rehabilitation

2

Description
Control group: Intervention group: 10 session of physiotherapy, three sessions per week, each session consist of below: 1)Sham PEMFS: Their elbows will be positioned the same way as with the Group 1 patients in the same applicator. However, the electric current producer will be connected to another solenoid applicator (small solenoid). The patient will sense the same visual and auditory stimuli like the patient taking the active therapy, but not exposed to the real magnetic field. 2)routine physiotherapy: Transcutaneous electrical nerve stimulation (TENS) , Low frequency TENS: 5 KHz modulated by 2 Hz frequency mode on acupuncture points , Infrared (IR) for 12 minutes on lateral aspect of elbow. Stretching , The Proprioceptive neuromuscular facilitation (PNF) stretching model was used with contraction for 10 seconds, short relaxation and then stretching for 15- 20 seconds of the forearm extensors (and the antagonist flexors subsequently), to be performed feeling the tightness, but below the pain threshold. Eccentric exercise: patient sitting on a chair, support the forearm on the armrest or on an adjacent table in prone position. The eccentric exercise is to lower the weight by flexing the wrist of the affected arm downwards and to lift it back again with the unaffected arm in three sets of 15 repetitions, in total 45 weight lowering manoeuvres. Ultrasound therapy: continuous ultrasonic waves of 1.5 MHz frequency and 1 W/cm2 power. The patients in the sitting position, and an acoustic gel containing no pharmacological active substance will be applied. Ultrasound will be applied to the lateral epicondyle in circular movements
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center,. Semnan University of Medical Scinces., Semnan., Iran.
Full name of responsible person
Dr Rasool Bagheri
Street address
Basij Blvd.,Semnan., Semnan Province
City
Semnan
Province
Semnan
Postal code
3513135111
Phone

+98 23 3336 4180

Email

rasool.bagheri@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid MirMohammadkhani

Street address

Semnan University of Medical Sciences, Basij Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

majidmirmohammadkhani@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Sahel aliannejadi

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Km 5 Damghan Road., Semnan University of Medical Sciences., School of Rehabilitation., Semnan town

City

Semnan

Province

Semnan

Postal code

3513135111

Phone

+98 23 3344 1022

Email

sahel.aliannejad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Rasool Bagheri

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Km 5 Damghan Road., Semnan University of Medical Sciences., School of Rehabilitation., Semnan town

City

Semnan

Province

Semnan

Postal code

3513135111

Phone

+98 23 3344 1022

Email

rasool.bagheri@ymail.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Rasool bagheri

Position

Assisstant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Km 5 Damghan Road., Semnan University of Medical Sciences., School of Rehabilitation., Semnan town

City

Semnan

Province

Semnan

Postal code

3513135111

Phone

+98 23 3344 1022

Email

rasool.bagheri@ymail.com

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