

# 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@gmail.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 diagnosis from 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/cm<sup>2</sup> 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/cm<sup>2</sup> 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 Sciences., Semnan., Iran.

#### **Full name of responsible person**

Dr Rasool Bagheri

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

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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**

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**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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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