

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of %1 hydrocortisone phonophoresis, low level laser and conventional therapy methods in the treatment of patients with lateral epicondylitis of elbow

#### Protocol summary

##### Summary

Lateral epicondylitis of elbow is the most common contractile lesion that causes inflammation and pain at the origin of the wrist extensor muscles. The aim of this study is comparing %1 hydrocortisone phonophoresis, low level laser and conventional therapy methods in the treatment of lateral epicondylitis of elbow. Seventy eight patients afflicted to lateral epicondylitis will refer to clinic of Fattemeh physiotherapy in Rafsanjan. Assessor evaluates the patients based on inclusion criteria, then he divided them to random permuted blocks methods in 3 equal groups and refers to therapist. Three methods of this study are %1 hydrocortisone phonophoresis (Ultrasound, ITO Japan with %1 hydrocortisone ointment), low power laser (GA AL AS, 810nm, 100mv) and conventional treatment of physiotherapy. Intensity of local pain, radicular pain, tenderness to palpation and grip strength are assessed during 1st, 5th, 10th sessions and 10 days after end of treatment. Inclusion criteria are pain at the origin of the wrist extensors muscles, radicular pain to forearm, tenderness at the origin of the wrist extensors. Exclusion criteria are previous fractures of humerus, radius and ulna, rheumatism arthritis of elbow, cervical disc herniation, disc degeneration and injection of corticosteroids. This study is a double blind clinical trial because both of patient and assessor are not aware of type of treatment methods but therapist is aware of type of treatment methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201507043220N6**

Registration date: **2015-09-03, 1394/06/12**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-03, 1394/06/12

##### Registrant information

###### Name

Dadollah Shahimoridi

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 39 1822 0040

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Rafsanjan University of Medical Sciences

##### Expected recruitment start date

2015-07-18, 1394/04/27

##### Expected recruitment end date

2016-05-16, 1395/02/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of %1 hydrocortisone phonophoresis, low level laser and conventional therapy methods in the treatment of patients with lateral epicondylitis of elbow

##### Public title

Effect of ultrasound associated with hydrocortisone and

laser on epicondylitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: pain at the origin of the wrist extensor muscles, radicular pain to forearm, tenderness at the origin of the wrist extensors. Exclusion criteria: previous fractures of humerus, radius and ulna, rheumatism arthritis of elbow, cervical disc herniation, disc degeneration and injection of corticosteroids

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **78**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double 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 Rafsanjan University of Medical Sciences

##### Street address

Rafsanjan University of Medical Sciences, Emam Ali street

##### City

Rafsanjan

##### Postal code

#### Approval date

2015-07-04, 1394/04/13

#### Ethics committee reference number

IR.RUMS.REC.9

## Health conditions studied

### 1

#### Description of health condition studied

Lateral epicondylitis of the elbow

## ICD-10 code

M77.1

## ICD-10 code description

Lateral epicondylitis

## Primary outcomes

### 1

#### Description

Tenderness

#### Timepoint

1st (before treatment), 5th, 10th sessions and 10 days after end of treatment

#### Method of measurement

By questionnaire

### 2

#### Description

Grip strength of hand

#### Timepoint

1st (before treatment), 5th, 10th sessions and 10 days after end of treatment

#### Method of measurement

By dynamometer

### 3

#### Description

Radicular pain

#### Timepoint

1st (before treatment), 5th, 10th sessions and 10 days after end of treatment

#### Method of measurement

By questionnaire

### 4

#### Description

Pain intensity at rest

#### Timepoint

1st (before treatment), 5th, 10th sessions and 10 days after end of treatment

#### Method of measurement

By Visual Analogue Scale(VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First group will receive %1 hydrocortisone phonphoresis by Ultrasound, (ITO, 7P, 1MHZ, Japan) that is apply through 1.5 w/cm2 intensity continuous wave and 5 minutes per sessions plus %1 hydrocortisone ointment during 10 sessions on lateral epicondyle of elbow.

#### Category

Rehabilitation

**2**

**Description**

Second group will receive low power laser (GAL AL AS, 810nm, 100 mv, 5J) intensity on lateral epicondyle of elbow

**Category**

Rehabilitation

**3**

**Description**

Third group will receive conventional treatment of physiotherapy (infrared 10 minutes, ultrasound 1.5 w/cm<sup>2</sup>, 5 minutes and TENS 15 minutes) during 10 sessions on lateral epicondyle of elbow.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of Fattemieh physiotherapy

**Full name of responsible person**

Dadollah Shahimoridi

**Street address**

**City**

Rafsanjan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Rafsanjan University of Medical Sciences

**Full name of responsible person**

Hamid Hakimi

**Street address**

Rafsanjan University of Medical Sciences, Emam Ali street

**City**

Rafsanjan

**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, Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dadollah Shahimoridi

**Position**

Academic member

**Other areas of specialty/work**

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**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*