Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 phonphoresis, 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 Fattemieh 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 phonphoresis (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
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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/cm2, 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
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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