Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Comparative effect of new physiotherapy with emphasis on shoulder and scapula exercises with traditional physiotherapy on pain, strength and disability outcomes in patients with lateral elbow tendinopathy

Protocol summary

Study aim
The purpose of our research is answer to this question: are shoulder and scapula muscles exersices plus local elbow exersice play a role on pain, strenght or disability in patients with lateral epicondylalgia? and to identify which patients may best benefit from this treatment approach; versus traditional physiotherapy (heat, friction massage, TENS, local elbow exersice.)

Design
Randomised balance, 40 patients divided 2 gruops, blinded

Settings and conduct
patients that come to private clinics or Quaem hospital

Participants/Inclusion and exclusion criteria
age 18-65 years pain score at the lateral side of the elbow at least 3 from 10 pain in at least two of the following four tests, 1- Cozen's Test 2- Mill's Test 3- pain on the facet of the lateral epicondyle when palpated or presured 4- resisted handgriped thorasic surgery neurologic and orthopedic diseases in shoulder, elbow or wrist Congenital disorder in elbow elbow injection in 1 month ago physiotherapy in 3 month ago Myofascial trigger points with radicular pain in elbow

Intervention groups
1- Traditional physiotherapy group (local exersice- IR- Heat- TENS) 2- New physiotherapy group (local elbow exersice- IR- Heat- TENS- shoulder and scapula exersice)

Main outcome variables
pain strenght function disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180720040532N1**
Registration date: **2018-08-11, 1397/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-11, 1397/05/20**
Update count: **0**

Registration date
2018-08-11, 1397/05/20

Registrant information

Name
Akram Divandari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3382 2252

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-01, 1397/04/10

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effect of new physiotherapy with emphasis on shoulder and scapula exercises with traditional physiotherapy on pain, strength and disability outcomes in patients with lateral elbow tendinopathy

Public title

comparative effect of 2 physiotherapy methodes in patients with tennis elbow

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age 18-65 years pain score at the lateral side of the elbow at least 3 from 10 pain in at least two of the following four tests, 1- Cozen's Test 2- Mill's Test 3- pain on the facet of the lateral epicondyle when palpated or presured 4- resisted handgriped

Exclusion criteria:
thorasic surgery neurologic and orthopedic diseases in shoulder, elbow or wrist Congenital disorder in elbow elbow injection in 1 month ago physiotherapy in 3 month ago Myofascial trigger points with radicular pain in elbow

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
we use pockets, we wrote methode of treatment in pockets and selected one of them.

Blinding (investigator's opinion)
Double blinded

Blinding description
patients don't know about 2 groups assessor doesn't know group's patient analysor doesn't know group's datas

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Azadi Squre

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2018-06-30, 1397/04/09

Ethics committee reference number
IR.MUMS.REC.1397.091

Health conditions studied

1

Description of health condition studied
lateral elbow tendinopathy

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
pain

Timepoint
pre- post

Method of measurement
Visual Analoge Scale

2

Description
strenght

Timepoint
pre- post

Method of measurement
handheld digital dynamometer

3

Description
function

Timepoint
pre-post

Method of measurement
Patient-related Tennis Elbow Evaluation Questionnaire

4

Description
disability

Timepoint
pre- post

Method of measurement
Disability Arm Shoulder Hand Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
control group: local elbow exersice
Category
Rehabilitation

2

Description
Intervention group: local elbow exersice+ scapula and shoulder exersice
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem Hospital, Physiotherapy section
Full name of responsible person
Javad Zarandi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaqqodi
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Neda Mostafaee
Position
Assistant Professor
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