Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Mulligan's techniques along with routine physiotherapy, in comparison with routine physiotherapy alone; on pain, grip strength, and function in patients diagnosed with chronic lateral epicondylitis

Protocol summary

Study aim

The objective of this study is to compare the effect of a combination of Mulligan's techniques and routine physiotherapy treatments, with that of routine physiotherapy alone; in patients diagnosed with chronic lateral epicondylitis of humerus.

Design

Single-blind, randomised, controlled clinical trial with a parallel group design of 17 patients, pain, maximum hand grip strength and functional disability, 12 sessions in 4 weeks, routine Physiotherapy, Mulligan's techniques and routine phsiotherapy, assessment at baseline and after treatment.

Settings and conduct

Patients with chronic lateral epicondylitis symptoms lasting more than 3 months, will participate in this study. A summary of the research methodology will be presented to the participants, and they will fill out the moral rights consent and information gathering forms. Participants will be randomly assigned to either the routine group of physiotherapy or the Mulligan group using the Web application (www.randomizer.org, version 4). 34 patients will undergo 12 sessions of treatment in 4 weeks, in the Physiotherapy Clinic of Iran Faculty of Rehabilitation. The outcomes (pain , maximum grip strength and functional disability) will be evaluated at baseline and after treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with chronic lateral epicondylitis symptoms lasting more than 3 months, with an average age of 35 - 55 years; who are referred by the physician Exclusion Criteria: Pain in the lateral humeral epicondyle due to neck involvement

Intervention groups

In this study, routine treatment includes ultrasound, strength training exercises and stretching exercises. The Mulligan group receives the Mulligan’s techniques using a treatment belt, along with routine physiotherapy.

Main outcome variables

pain, functional disability and grip strength.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043058N1**
Registration date: **2019-04-26, 1398/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-26, 1398/02/06**
Update count: **0**

Registration date

2019-04-26, 1398/02/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Mulligan's techniques along with routine physiotherapy, in comparison with routine physiotherapy alone; on pain, grip strength, and function in patients diagnosed with chronic lateral epicondylitis

Public title
The effect of Mulligan's techniques in the treatment of chronic lateral epicondylitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic lateral epicondylitis symptoms lasting more than 3 months, with an average age of 35 - 55 years who are referred by the physician Pain intensity of at least 3, in the lateral epicondyle of the humerus bone, which demonstrates an increase of 2 units by griping and active wrist extension, and decreases with rest. Pain intensity is assessed using numeric pain rating scale (NPRS) measure Positive Mill’s test (passive stretching): The physiotherapist touches the lateral epicondyle with one hand, while with the other hand pronates the patient's forearm and flexes the wrist to the maximum flexion and extends the elbow. Reproduction of pain indicates that the test is positive Positive Cozen's test (wrist resistive extension test): The wrist resistive extension and radial deviation and forearm pronation tests are performed. In case the test triggers pain, the test is considered positive Positive Maudsley's test: A positive test is indicated by presence of pain over the lateral epicondyle of the affected hand during the third finger resistive extension test Presence of tenderness at the tenoperiosteal junction or at the junction of the extensor carpi radialis brevis muscle to the lateral humeral epicondyle
Exclusion criteria:
Pain in the lateral humeral epicondyle, due to neck involvement Lateral humeral epicondyle acute inflammation Pain in the lateral humeral epicondyle, caused by acute trauma of elbow region Radial tunnel syndrome Elbow joint inflammation Injuries to the internal and external ligaments of the elbow Medial humeral epicondylitis History of elbow joint bone fractures Presence of deformity or congenital anomalies of the elbow joint Pregnancy Infection of the elbow joint Malignancies Hemophilia Generalised hypermobility Presence of swelling in the elbow joint Presence of myositis ossification in radiographic x-ray Dissatisfaction of participants Trigger points in the wrist and finger extensor muscles
Age
From **35 years** old to **55 years** old
Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly assigned to either the routine group of physiotherapy or the Mulligan group using the Web application Randomizer (www.randomizer.org, version 4).
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind study. In a single-blind study, only the therapist and assessor are aware of the make up of the treatment groups and the participants are unaware of the the treatment group they are assigned to.
Placebo
Not used
Assignment
Parallel
Other design features
This study is a single-blind randomised controlled clinical trial with continuous non-random and purposive (subjective) sampling. The study is at Level Ib, which is the highest level of clinical trials in the Evidence-Based Medicine (EBM) pyramid.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
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Approval date
2018-10-02, 1397/07/10
Ethics committee reference number
IR.IUMS.REC.1397.277

Health conditions studied

1

Description of health condition studied
Chronic Lateral Epicondylitis

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
The outcomes of the study will be measured at baseline and after 12 sessions of treatment and the results of the two groups will be compared.
Method of measurement
In this study, a 100 mm Numeric Pain Rating Scale (100 mm NPRS) is used to measure pain. The patients are asked to place a mark along a 100-mm scale to indicate the average elbow pain they had suffered in the last 24 hours while resting.

2

Description
Functional Disability
Timepoint
The outcomes of the study will be measured at baseline and after 12 sessions of treatment and the results of the two groups will be compared.
Method of measurement
In order to evaluate the functional status of participants, a Persian version of the Patient-Rated Elbow Evaluation Questionnaire is used. The questionnaire contains 5 questions about pain domain and 15 questions about functional limitations domain during everyday life, work and exercise.

3

Description
Grip Strength
Timepoint
The outcomes of the study will be measured at baseline and after 12 sessions of treatment and the results of the two groups will be compared.
Method of measurement
Maximum grip strength is evaluated using the SHE 1001 SAEHAN handheld digital hydraulic dynamometer.

Secondary outcomes

1

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Control group: A total of 34 patients are enrolled in this study. The control group consists of 17 patients who receive routine treatment for 12 sessions in 4 weeks. In the current study, the routine treatment includes ultrasound, strengthening and stretching exercises. Patients in this group receive ultrasound with a frequency of 3 Mhz and intensity of 1.5 w/cm2 in pulsed mode of operation and the pulse is 1ms on and 5ms off. The area of the transducer head is 4 square centimeters (4cm2). The transducer head is placed on the junction of the extensor carpi radialis brevis tendon for 5 minutes. The strengthening exercises are in the form of eccentric strengthening exercises. In the early sessions, exercises are carried out with low-load and high-repetition. Three principles are taken into account in strengthening exercises: the exercise load intensity, the speed, and the frequency of exercises. The exercise load intensity and the speed of strengthening exercises are adjusted according to the symptoms severity of the patients in various treatment sessions. However, The frequency of exercises is three sets of ten repetitions per session. The strengthening exercises are performed with the patient's elbow in the extension and the forearm in the pronation, while the physiotherapist moves the patient's wrist in the flexion direction and the patient resists against the movement using eccentric contraction. Passive and static stretching exercises are performed by an expert physiotherapist with more than 15 years of experience in the treatment of patients with chronic lateral epicondylitis. To perform the exercises, the patient's elbow is placed in the extension and the forearm in the pronation. The physiotherapist flexes the patient's wrist passively and holds it for 30 - 45 seconds. The number of repetitive stretching exercises is set to six repetitions, with a 15 second rest interval between two stretching exercises; based on the Fyfe and Stanish study.
Category
Rehabilitation

2

Description
Intervention group: The intervention group (the Mulligan treatment group) consists of 17 patients. The Mulligan treatment group receives the routine treatment along with Mulligan's techniques. Patients receive two Mulligan's techniques in the extension and flexion positions. Mulligan's technique in the extension position: To perform the Mulligan's technique, the patients are placed in the supine position with their elbow in the extension and their forearm in the pronation, so that the radiohumeral joint is perpendicular to the ground. The Mulligan belt passes under the articular surface of the elbow joint and around the radiohumeral joint and wraps around the physiotherapist’s shoulder. The physiotherapist stabilises the distal part of the forearm on the bed with one hand and holds the distal part of the humerus bone in a fixed position, with the other hand. Simultaneously, the therapist applies an upward force, perpendicular to the ground by lifting up on the forefoot. While applying the force, the patients are asked to make a full fist to the maximum strength. The force is applied for 6 seconds and then the patients are asked to release their fingers. This technique is applied 10 times and

while it is applied, no pain should be reported by the patient. Mulligan's technique in the flexion position: To perform this technique, the patient is placed in the supine position. The patient's elbow is flexed at 90 degree, and the Mulligan belt passes under the proximal forearm of the patient and wraps around the pelvis of the physiotherapist. The physiotherapist stabilises the distal part of the forearm on the bed with one hand and holds the distal part of the humerus bone in a fixed position with the other hand to prevent the movement of different parts, while applying the technique. Then the physiotherapist applies a downward force to the proximal forearm by moving his pelvis backwards. The duration of the force is 6 seconds and the technique is applied 10 times. Care should be taken so that the patient does not report any increase in pain, during the application of the technique.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The current study is fully funded by Mohammad Asadi.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data collected for the primary and secondary outcome measures is shared after anonymising participants, if required.

When the data will become available and for how long
The data is accessible 6 months after publishing the outcomes of the study.

To whom data/document is available
The data is accessible to physical therapists working in academic institutions as well as clinicians working in the field of musculoskeletal disorders.

Under which criteria data/document could be used
The raw data and the results of this study might be used in the future relevant research studies and systematic reviews. Hence, the raw data and the results of this study are accessible to researchers working in the field of elbow lesions.

From where data/document is obtainable
Please send your access requests to Mohammad Asadi (PT, MSc student). Email address: ptdrasadi@gmail.com

What processes are involved for a request to access data/document
Researchers should describe their project in detail and explain how the data/documents of this study will be used in their project. Following the request, the data/document files will be sent to researchers by email. This process might take 10 - 12 working days.

Comments