Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effects of Kinesio taping, Counterforce brace and Corticosteroid injection on common extensor tendon thickness and pain intensity in patients with tennis elbow.

Protocol summary

Study aim

Comparing the effects of kinesio taping, counterforce brace and corticosteroid injection on common extensor tendon thickness and pain intensity in patients with tennis elbow.

Design

This study will be conducted as a randomized clinical trial with a parallel group design. The grouping in this study is random and the patients are placed in one of three treatment groups: Kinesiotape, Counterforce Brace and Corticosteroid injection. Randomization will be done by Permuted block randomization method.

Settings and conduct

Patients are randomly assigned to one of the three treatment groups, and before and after treatment interventions, measurement criteria are evaluated in Shahid Beheshti Hospital, Babol.

Participants/Inclusion and exclusion criteria

Tenderness and pain in the external epicondyle Positive tests (Maudsley's test/ Mill's test/ Cozen's test) Age above 18 years Having symptoms of the disease for at least 4 weeks to 6 months (patients with mild to moderate severity of this disease) Exit criteria: Radiculopathy pains and cervical spondylolysis diabetes Polyneuropathy or entrapment neuropathies History of surgery or acute trauma to the elbow Rheumatoid arthritis diseases History of steroid injection or physiotherapy in the lateral epicondyle of the humerus Acuteness of the condition (severe tenderness, pain during normal active movements, warmth of the epicondyle position) History of surgery or elbow sprain Pregnancy Cancer

Intervention groups

Patients are randomly assigned to one of three treatment groups: kinesiotape, counterforce brace, or corticosteroid injection group.

Main outcome variables

Measurement of extensor tendon thickness and The visual analogue scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091214002851N7**
Registration date: **2022-08-12, 1401/05/21**
Registration timing: **prospective**

Last update: **2022-08-12, 1401/05/21**
Update count: **0**

Registration date

2022-08-12, 1401/05/21

Registrant information

Name

Mohammad Taghipour

Name of organization / entity

Babol University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-16, 1401/06/25

Expected recruitment end date

2023-06-15, 1402/03/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of Kinesio taping, Counterforce brace and Corticosteroid injection on common extensor tendon thickness and pain intensity in patients with tennis elbow.

Public title
Comparing the effects of Kinesio taping, Counterforce brace and Corticosteroid injection in tennis elbow
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tenderness and pain in the external epicondyle Positive tests (Maudsley's test/ Mill's test/ Cozen's test) Age above 18 years Having symptoms of the disease for at least 4 weeks to 6 months (patients with mild to moderate severity of this disease)
Exclusion criteria:
Radiculopathy pains and cervical spondylolysis Diabetes Polyneuropathy or entrapment neuropathies History of surgery or acute trauma to the elbow Rheumatoid arthritis diseases History of steroid injection or physiotherapy in the lateral epicondyle of the humerus Acuteness of the condition (severe tenderness, pain during normal active movements, warmth of the epicondyle position) History of surgery or elbow sprain Pregnancy Cancer
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by Permuted block randomization method. The size of each block is considered to be 6. There are equal numbers of each group in each block. In addition, the order of placement of three treatments in each block is random and determined by a statistician. The letters A, B, and P are written in the letter envelopes, and the patients randomly pick an envelope, and based on that, their treatment group is determined. Patients who remove letter A envelope are placed in the Counterforce brace treatment group, patients who remove letter B envelope are placed in the Kinesiotape treatment group, and patients who remove envelope P are placed in the Corticosteroid injection group. A random code is written on each envelope, and when people enter the study, an envelope (in the above order) is assigned to them. The code on the envelope will be written on the patient's file (checklist).
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, which will be conducted as a randomized controlled trial or RCT, the evaluator and the therapist are two different people. Therefore, this study is a single-blind study. Also, the statistical analyst is not aware of the grouping.
Placebo
Not used
Assignment
Parallel
Other design features
Comparing the effects of Kinesio taping, Counterforce brace and Corticosteroid injection on common extensor tendon thickness and pain intensity in patients with tennis elbow.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Mazandaran, Babol, Ganj Afrooz St., Babol University of Medical Sciences
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Babol
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Postal code
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Approval date
2022-07-25, 1401/05/03
Ethics committee reference number
IR.MUBABOL.HRI.REC.1401.097

Health conditions studied

1

Description of health condition studied
Tennis elbow
ICD-10 code
M77.1
ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Measurement of the thickness of the common extensor tendon
Timepoint
Before treatment. After treatment and two weeks after treatment
Method of measurement
Ultrasound machine

2

Description
Pain measurement
Timepoint
Before treatment. After treatment and two weeks after treatment
Method of measurement
visual analogue scale (VAS)

Secondary outcomes

1

Description
The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire
Timepoint
Before treatment. After treatment two weeks after treatment
Method of measurement
DASH questionnaire

2

Description
Measurement of wrist and finger flexsor muscle strength
Timepoint
Before treatment. After treatment two weeks after treatment
Method of measurement
Dynamometer device

Intervention groups

1

Description
Intervention group: Counterforce Brace group: Patients will be asked to show the pain point on the elbow, and then we will tie the Counterforce Brace 5 cm below the elbow crease. Next, patients are requested to perform elbow flexion and extension movements in order to ensure that the range of motion of the elbow is not limited following the use of the Counterforce Brace. Patients will also be asked to grip with a lot of force to make sure the brace is not too tight. Each patient will use Counterforce Brace for two weeks. The patient only removes the Counterforce brace from the elbow while sleeping and washing. The Counterforce brace available in the market will be used in this study.
Category
Treatment - Devices

2

Description
Intervention group: Kinesiotape group: To use kinesiotape to restrain the muscle, we use two Y-shaped bands. The main strip along the length of the extensor carpi radialis brevis muscle and the common extensor from the distal part of the muscle to its proximal side and the second strip is attached in order to correct the fascia, with maximum tension perpendicular to the main strip in the upper part of the forearm. The position of the patient's upper limb is placed in the form of elbow extension and flexion and wrist deviation to the ulnar side. The beginning and end of the main group must be connected without tension. But in placing the tape along the length of the muscle, it should be attached with 30% tension. Types are changed every 3 days for two weeks. In total, each patient receives kinesiotape 4 times. The patients in this group were asked to avoid direct contact of the forearm with water as much as possible. In this study, kinesiotape brand bio balance tape will be used.
Category
Treatment - Devices

3

Description
Intervention group: Corticosteroid injection group: In this group, after the initial assessment, the orthopedic doctor administered a single corticosteroid injection to the patients along with lidocaine (one milliliter of methylprednisolone ten milligrams and one milliliter of two percent perilucaine) at the pain site. will be The patient's elbow is placed in a position of 45 degrees of flexion and forearm pronation on a hard place. The needle is inserted vertically into the pain area to hit the bone. Then half of the amount that entered the body is removed and the injection is performed. No other intervention methods, including physiotherapy and oral drugs, are prescribed to patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic and Physiotherapy clinic of Shahid Beheshti hospital
Full name of responsible person
Mohammad Taghipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Babol 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
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Full name of responsible person
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Position
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Bachelor
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Person responsible for updating data

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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

All data can potentially be shared after unidentified individuals

When the data will become available and for how long

Access period starts 2 months after the results are published

To whom data/document is available

Researchers working in academic, scientific and medical institutions

Under which criteria data/document could be used

To cite other researchers from the results of our research

From where data/document is obtainable

Dr. Mohammad Taghipour, Babol University of medical sciences, college of Rehabilitation, 00989126899352 ,taghipour@mubabol.ac.ir Seyyed Mohammadreza Hoseini. Babol University of medical sciences, college of Rehabilitation ,00989361182439mohammadreza.seyyed.1377@gmail.com

What processes are involved for a request to access data/document

2-4 weeks after request by email

Comments