

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Iran (Islamic Republic of)

Phone

+98 11 3219 4641

Email address

taghipour@mubabol.ac.ir

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

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 flexor 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 prilucaine) 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

Street address

Keshvari Square, Sargord Ghasemi St., Shahid Beheshti Hospital, Physiotherapy Center

City

babol

Province

Mazandaran

Postal code
4716681451
Phone
+98 11 3226 0458
Email
beheshti@mubabol.ac.ir
Web page address
<https://beheshti.mubabol.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Mehdi Rajabnia
Street address
Mazandaran, Babol, Ganj Afrooz St, Babbol university
of medical science
City
babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 7667
Email
research@mubabol.ac.ir
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

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyyed Mohammadreza Hoseini
Position
student
Latest degree
Bachelor
Other areas of specialty/work

Physiotherapy
Street address
Babol university of medical science, college of
Rehabilitation
City
Babol
Province
Mazandaran
Postal code
47745-47176
Phone
+98 11 3219 4641
Email
Mohammadreza.seyyed.1377@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Mohammad Taghipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Babol university of medical science, college of
Rehabilitation
City
Babol
Province
Mazandaran
Postal code
47745-47176
Phone
+98 11 3219 4641
Email
taghipour@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyyed Mohammadreza Hoseini
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Babol university of medical science, college of
Rehabilitation
City
Babol
Province

Mazandaran

Postal code

47745-47176

Phone

+98 11 5221 8865

Email

Mohammadreza.seyyed.1377@gmail.com

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