

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The immediate effects of counterforce brace with and without vibration on pain, range of motion, grip strength and wrist extensor muscles strength in participant with tennis elbow

Protocol summary

Study aim

Evaluation of the immediate effect of the counterforce brace with and without vibration on pain, range of motion, grip strength and wrist extensor muscles strength in tennis elbow. Comparison of the immediate effect of the counterforce brace with and without vibration on pain, range of motion, grip strength and wrist extensor muscles strength in tennis elbow.

Design

Interventional study, without control group and blinding

Settings and conduct

The variables are measured before the intervention. The patients are given counterforce and after the brace is closed on the site and the patient is comfortable, the variables are measured. The brace is removed (to eliminate its impact by a 5-minute interval that is approximately 15 minutes to ensure this time) and the brace with vibration are positioned at the desired location and the variables are measured again. Because of the probability of the vibration effect remaining, all patients will first be treated with a conventional counterforce and a second brace with vibration.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people with tennis elbows; age between 20 to 60 years old; no history of surgery, cervical disc, elbow fracture; without rheumatic diseases and peripheral neuropathy.

Intervention groups

Intervention group I: counterforce brace without vibration that closes 2.5 cm below the elbow. Intervention group II: counterforce brace with vibration with frequency of 30 to 50 Hz, 2.5 mm amplitude and intensity tolerable for the patient that closes 2.5 cm below the elbow.

Main outcome variables

Pain; grip strength; range of motion; wrist extensor muscles strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040148N3**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

Registration date

2020-01-13, 1398/10/23

Registrant information

Name

Masumeh Bagherzadeh Cham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1612

Email address

bagherzadehcham.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate effects of counterforce brace with and without vibration on pain, range of motion, grip strength and wrist extensor muscles strength in participant with tennis elbow

Public title

The immediate effects of counterforce brace with and without vibration in participant with tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with tennis elbows according to the diagnosis of a specialist physician and standard diagnostic criteria Age 20 to 60 years old

Exclusion criteria:

History of surgery, cervical disc and elbow fracture
Rheumatic diseases and peripheral neuropathy

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: **27**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.IUMS.REC.1398.880

Health conditions studied

1

Description of health condition studied

Tennis elbow

ICD-10 code

M77.1

ICD-10 code description

Tennis elbow, Counterforce brace, Vibration, Lateral epicondylitis

Primary outcomes

1

Description

Pain

Timepoint

Measurement of pain before intervention, after the first intervention and after the second intervention

Method of measurement

Visual analog scale and algometer for measuring pain

2

Description

Range of motion

Timepoint

Measurement of range of motion before intervention, after the first intervention and after the second intervention

Method of measurement

Goniometer for measuring range of motion

3

Description

Grip strength

Timepoint

Measurement of grip strength before intervention, after the first intervention and after the second intervention

Method of measurement

Dynamometer to measure grip strength

4

Description

Wrist extensor muscles strength

Timepoint

Measurement of strength of wrist extensor muscles before intervention, after the first intervention and after the second intervention

Method of measurement

Digital dynamometer for measuring the strength of wrist extensor muscles

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Brace counterforces, 5 minutes on the patient's hand, Location: 2.5 cm below the elbow.
Intervention group II: Counterfeit brace with vibration, frequency 30-50 Hz, 2.5 mm amplitude, patient tolerance intensity for 5 minutes, location: 2.5 cm below elbow

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar hospital

Full name of responsible person

Masumeh Bagherzadeh Cham

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Valiasr Square, Karim Khan St., Beh Afarin St.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masumeh Bagherzadeh Cham

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Rehabilitation management

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Person responsible for updating data

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Rehabilitation management

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

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

Title and more details about the data/document

All data can be shared after unidentifiable people

**When the data will become available and for how
long**

Starting one year after article publication

To whom data/document is available

Information is available to all researchers working in
academic and scientific institutions

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and
organizational affiliation of the correspond and co-author
of the project and the published article.

From where data/document is obtainable

Connect to Dr Masumeh Bagherzadeh Cham by email:
masumehbagherzadeh@gmail.com

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

If information is used in scientific and therapeutic
activities, information is provided as soon as possible.

Comments