Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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: counterforse brace without vibration that closes 2.5 cm below the elbow. Intervention group II: counterforse 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 epicondilitis

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 counterforses, 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., Firoozgar Hospital
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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
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
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Orthotics and Prosthetics
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Person responsible for scientific inquiries

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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
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