

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Protocol summary

Study aim

The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Design

A Clinical trial with two control and treatment groups, with Parallel groups, single-blind, Randomization sequence was through randomization.com and balanced block randomization method.

Settings and conduct

Rehabilitation Tehran University of Medical Sciences, evaluation and treatment were performed in the control group and in the intervention group for 4 weeks and re-evaluated 48 hours after the last treatment session. The analyzer is not aware of the patient information group

Participants/Inclusion and exclusion criteria

Inclusion Criteria 18-40 years old Both genders Have a history of anterior cruciate ligament surgery (hamstring graft) without surgery for other ligament and meniscus injuries More than 6 months have passed since the surgery Edinburgh handedness inventory (EHI) questionnaire Tegner Activity Level Scale < 8 had no pain, inflammation or limited range of motion in the knee joint Team doctor approval WBV contraindication TMS contraindication Exclusion Criteria Inability to understand and/or perform the required maneuvers. Alcohol, caffeine and drug consumption on the day of the test. Participant dissatisfaction with the continuation of the program. Being absent for more than 2 sessions or for 3 times

Intervention groups

1- treatment group 2- control group. both groups are athletes with ACL Reconstruction surgery that take 12 treatment sessions. Treatment protocol for treatment group is exercise therapy and whole body vibration. Control group only take exercise therapy

Main outcome variables

Central Activation Ratio, Active Motor Threshold, Amplitude of Motor Evoked Potentials, Map Volume, Center of Gravity, 6m-Timed Hop Test Limb Symmetry Index, KOS-ADL Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220220054078N1**

Registration date: **2022-04-11, 1401/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

Registration date

2022-04-11, 1401/01/22

Registrant information

Name

Sahar Zare pourhashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 4268

Email address

sahar.zp798@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Whole body vibration on muscle inhibition, cortical excitability and topographic map of quadriceps muscle in the brain of athletes following anterior cruciate ligament reconstruction

Public title
investigating the effect of Whole body vibration in athletes following anterior cruciate ligament reconstruction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18-40 years old both of gender III More than 6 months have passed since the surgery Edinburgh handedness inventory (EHI) questionnaire Tegner Activity Level Scale < 8 Have a history of anterior cruciate ligament surgery (all types of graft) without surgery for other ligament and meniscus injuries had no pain, inflammation or limited range of motion in the knee joint WBV contraindication: pregnancy, acute thrombosis, serious cardiovascular disease, pacemaker, acute hernia, discopathy, spondylolysis, severe diabetes, epilepsy, recent infections, severe migraine, tumors or kidney stones. TMS contraindication: having a history of seizures, epilepsy (first-degree person or family), head injury or brain injury, having metal in the head (outside the mouth) such as a surgical clip, implantation Welded cochlear implants, history of a bad reaction to an MRI or TMS, history of stroke, brain-related diseases such as MS or brain tumor, history of fainting, severe headache, pregnancy Or planning for pregnancy in the past 3 months, taking medications known to lower the seizure threshold such as imipramine & Have a history of anterior cruciate ligament surgery (hamstring graft) without surgery for other ligament and meniscus injuries
Exclusion criteria:
 Inability to understand and/or perform the required maneuvers. Alcohol, caffeine and drug consumption on the day of the test. Participant dissatisfaction with the continuation of the program. Presence of pain at the time of the tests or any complication preventing the data collection. Being absent for more than 2 sessions or for 3 times during the whole procedure

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
individuals are randomly divided into two groups, which will be done using randomization sequence through randomization.com and balanced blocked randomization method. the size of the blocks is 4. also, for allocation concealment, sealed and numbered envelopes are used which are provided to the participants by the secretary.

Blinding (investigator's opinion)
Single blinded

Blinding description
patients are randomly divided into 2 groups of real treatment and control group who do not know the type of their group. the information obtained from the evaluation of patients is categorized by another person and analyst is not aware of the grouping of information.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
School of Rehabilitation, corner of Safi Alishahi street, Pich E Shemi, Enghelab street
City
Tehran
Province
Tehran
Postal code
1148956111

Approval date
2022-02-17, 1400/11/28

Ethics committee reference number
IR.TUMS.FNM.REC.1400.206

Health conditions studied

1

Description of health condition studied
athletes following anterior cruciate ligament reconstruction

ICD-10 code
S83.51

ICD-10 code description
Sprain of anterior cruciate ligament of knee

Primary outcomes

1

Description

Central Activation Ratio

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Biodex & stimulator

2

Description

Active Motor Threshold

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Transcranial magnetic stimulation (MagPro X100)

3

Description

Amplitude of Motor Evoked Potentials

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Transcranial magnetic stimulation (MagPro X100)

4

Description

Map Volume of quadriceps muscle in motor cortex

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Transcranial magnetic stimulation (MagPro X100)

5

Description

Center of Gravity of quadriceps muscle's map in motor cortex

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Transcranial magnetic stimulation (MagPro X100)

6

Description

6m-Timed Hop Test Limb Symmetry Index

Timepoint

At the start of the study and 48 hours after end of the

treatment

Method of measurement

By using chronometer

7

Description

Disability in Activities of Daily Living

Timepoint

At the start of the study and 48 hours after end of the treatment

Method of measurement

By using Knee Outcome Survey Activities of Daily Living Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

treatment group: Whole body vibration and exercise therapy including resistive exercises and perturbation exercises for 12 sessions in 4 weeks

Category

Rehabilitation

2

Description

Control group: exercise therapy including resistive exercises and perturbation exercises for 12 sessions in 4 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation school of Tehran university of medical Sciences

Full name of responsible person

Roya Khanmohammadi

Street address

School of Rehabilitation, corner of Safi Alishahi street, Pich E Shemi, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148956111

Phone

+98 21 7753 5132

Email

rkhanmohammadi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotoohi

Street address

Deputy of research and Technology, sixth floor,
Central University Organization, Corner of Quads
street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

6511111489

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Roya Khanmohammadi

Position

Proffessor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, corner of Safi Alishahi street,
Pich E Shemi, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148956111

Phone

+98 21 7753 5132

Email

rkhanmohammadi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Roya Khanmohammadi

Position

Professor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, corner of Safi Alishahi street,
Pich E Shemi, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148956111

Phone

+98 21 7753 5132

Email

rkhanmohammadi@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahar Zare pourhashemi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, corner of Safi Alishahi street,
Pich E Shemi, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148956111

Phone

+98 21 7753 5132

Email

sahar.zp798@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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