

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The increasing effect of transcranial direct current stimulation of the motor cortex to routine physical therapy on quadriceps muscle strength in athletes with anterior cruciate ligament reconstruction surgery: a double-blind randomized clinical trial.

Protocol summary

Study aim

Comparison of the effect of transcranial direct current stimulation (tDCS) of the motor cortex with routine treatments on quadriceps muscle strength in athletes with ACLR surgery

Design

Double-blind (subject and experimenter) randomized clinical trial

Settings and conduct

Adult male athletes with a history of unilateral ACLR using hamstring autografts were invited to the study through invitations posted in physiotherapy clinics, hospitals in Isfahan. Obtaining entry and exit criteria are selected by non-random and available sampling method. Eligible people enter the study after completing the informed consent form and will be randomly assigned to one of the intervention and sham groups. all the participants complete the personal information questionnaire, KOOS, IKDC, ACL-RSI and VAS questionnaire The tests are done in the sports science laboratory of Isfahan University and the intervention is done in a private physiotherapy clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: Athletes who have been at least 8 weeks and at most 3 months since their surgery
Exclusion criteria: 1. Knee surgery before ACLR 2. Lower extremity injury in the past 6 months other than current ACLR 3. Heart disease, history of stroke 4. Brain surgery, brain cancer and cranial nerves 5. Migraine 6. epilepsy or convulsive crises 7. Metal clips inside the skull 8. Cochlear implants or other implanted electronic devices 9. Impaired balance or dizziness 10. Any active skin infection 11. Taking sleeping pills or drugs that alter nerve activity within 48 hours before the evaluation

Intervention groups

Male athletes 18,40 years old with a history of unilateral

ACLR surgery

Main outcome variables

Muscle torque IKDC questionnaire score ACL-RSI questionnaire score KOOS questionnaire visual pain scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231113060048N1**

Registration date: **2023-12-28, 1402/10/07**

Registration timing: **prospective**

Last update: **2023-12-28, 1402/10/07**

Update count: **0**

Registration date

2023-12-28, 1402/10/07

Registrant information

Name

Naeemeh Haddadi esfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 2603

Email address

pt_nhaddad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The increasing effect of transcranial direct current stimulation of the motor cortex to routine physical therapy on quadriceps muscle strength in athletes with anterior cruciate ligament reconstruction surgery: a double-blind randomized clinical trial.

Public title

The increasing effect of transcranial direct current stimulation of the motor cortex to routine physical therapy on quadriceps muscle strength in athletes with anterior cruciate ligament reconstruction surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Athletes who have been at least 4 weeks and at most 3 months since their anterior cruciate ligament surgery

Exclusion criteria:

Knee surgery before ACLR Lower extremity injury in the past 6 months other than current ACLR Heart disease, history of stroke, and any problem that has a significant effect on a person's motor function or activity capacity Brain surgery, brain and cranial nerve cancer Migraine Medical records or personal reports of epilepsy or convulsive crises Metal clips inside the skull Cochlear implants or other implanted electronic devices Disturbance of balance or dizziness any active skin infection; or sensitivity to adhesive tape Taking sleeping pills or drugs that alter nerve activity within 48 hours before the evaluation

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **10**
10

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Randomization is done in such a way that qualified and available people are placed random in the intervention and sham groups. The researcher will perform all assessments and another person blind to the details of the study will apply both types of stimulation (active/sham). To achieve double-blinding, we will ensure that participants are unaware of the nature of the interventions and the assessor is unaware of participant grouping. To achieve this goal, tDCS interventions will be performed by one person and the baseline treatment and assessment of participants will be performed independently by another person, before and after the intervention.

Placebo

Used

Assignment

Parallel

Other design features

It seems that the measurement of central activation ratio in athletes with anterior cruciate ligament surgery in the acute phase (two months after surgery) will be done for the first time

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

9th Unit, 4th Floor, Iran Zamin Building, 10th Alley, Mulla Sadra Street, Esfahan

City

Esfahan

Province

Isfahan

Postal code

8168635978

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.163

2**Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

9th Unit, 4th Floor, Iran Zamin Building, 10th Alley, Mulla Sadra Street, Esfahan

City

Esfahan

Province

Isfahan

Postal code

8168635978

Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.163

Health conditions studied

1

Description of health condition studied

anterior cruciate ligament reconstruction surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

quadriceps muscle strength

Timepoint

Before application of tDCS current and after ten sessions of application of tDCS current

Method of measurement

Biodex Isokinetic Dynamometer

Secondary outcomes

1

Description

"Mental preparedness of athletes", "Evaluation of clinical symptoms and performance during sports activities and general performance", "Evaluation of pain and function in daily activities", "Assessment of pain intensity" and "Central activation ratio"

Timepoint

Before applying tDCS and after ten sessions of applying tDCS

Method of measurement

ACL-Return to Sport after Injury questionnaire , International Knee Documentation Committee questionnaire , Knee Injury and Osteoarthritis Outcome Score, Visual Analog Scale and Superimpose burst technique for Central Activation Ratio

Intervention groups

1

Description

After conducting the pilot project and determining the number of participants, those who meet the inclusion criteria will be randomly divided into two groups: routine physiotherapy plus anodal-tDCS and routine physiotherapy plus sham-tDCS. A dynamometer will be used to measure the strength of the quadriceps muscle. The dynamometer allowed the research team to measure maximal voluntary isometric contractions before and after the application of tDCS in athletes with

anterior cruciate ligament surgery. First, the isometric strength will be evaluated using a dynamometer by collecting the maximum voluntary force of the quadriceps muscles. To assess quadriceps muscle strength, participants will first be asked to perform a 5-minute warm-up exercise on an ergometric bicycle. Then sit on the dynamometer device so that the hip joint is bent at 90 degrees and the knee joint at 90 degrees. Restraint straps will be tightened around the waist and shoulders of each participant to control additional movement during the extension. The tibia, just near the ankle joint, on the anterior surface of the lower limb, 5 cm above the external ankle, is attached with Velcro straps to a pad on the arm of the dynamometer. The participants are told to cross their arms over the chest the entire time during the contractions to avoid unwanted involvement of the upper limbs during the test. Once the participants are properly positioned on the dynamometer, they will perform 2 submaximal voluntary isometric contractions of the knee extensors to familiarize themselves with the methods of assessing muscle strength. These contractions will not be recorded. Then they practice maximal contractions (without electrical stimulation) until the researcher and the subject are sure that the maximal effort is being performed. The participants then perform eight maximal voluntary isometric contractions for the quadriceps femoris in the extension direction with verbal feedback. Through verbal feedback, the patient should be asked to push with maximum effort (with at least 90 seconds of rest between tests). In this research, to perform the CAR test (by FES current), eight times the maximum voluntary isometric contraction of the quadriceps muscle will be performed for six seconds, and after observing and recording a constant value in the amount of torque, electrical stimulation will be applied during the maximum voluntary isometric contraction. This would, in theory, activate the remaining motor units that the patient was unable to perform during their maximal isometric muscle contraction. Electrical stimulation will consist of a group of waves consisting of ten square pulses with a pulse frequency of 100 pps and a pulse deviation of 0.6 milliseconds, with the stimulation intensity set to 2 times the motor threshold of use. The average maximum contractions with and without electric current will be calculated and the amount of voluntary muscle activation will be obtained by the formula. These steps will be done again after 10 sessions of anodal and sham tDCS stimulation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasti physiotherapy center

Full name of responsible person

Naeemeh Haddadi Esfahani

Street address

Unit 212, 2nd Floor, Ayrik Building, Noorollahi Alley,
North Sheikh Sadouq St, Esfahan

City

Esfahan

Province

Isfahan

Postal code

5581081311

Phone

+98 31 3664 5124

Email

pt_nhaddad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naeemeh Haddadi Esfahani

Street address

9th Unit, 4th Floor, Iran Zamin Building, 10th Alley,
Mulla Sadra Street, Esfahan

City

Esfahan

Province

Isfahan

Postal code

8168635978

Phone

+98 31 3670 2603

Email

pt_nhaddad@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naeemeh Haddadi Esfahani

Position

PHD candidate for physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

9th Unit, 4th Floor, Iran Zamin Building, 10th Alley,
Mulla Sadra Street, Esfahan

City

Esfahan

Province

Isfahan

Postal code

8168635978

Phone

+98 31 3670 2603

Email

pt_nhaddad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rostayi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Shahid Beheshti University of Medical Sciences,
Faculty of Rehabilitation Sciences, in front of Bo Ali
Hospital, Imam Hossein Square, Damavand Street,
Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1408

Email

roosta@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naeemeh Haddadi Esfahani

Position

PHD candidate of physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

9th Unit, 4th Floor, Iran Zamin Building, 10th Alley,
Mulla Sadra Street, Esfahan

City

Esfahan

Province

Isfahan

Postal code

8168685131

Phone

+98 31 3670 2603

Email

pt_nhaddad@yahoo.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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In this study, data on quadriceps muscle strength before and after ten sessions of tDCS will be shared after de-identification of subjects

When the data will become available and for how long

This data will be available after the completion of the work up to six months after the publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is nothing wrong with using the data for systematic review

From where data/document is obtainable

For contact information, please refer to the email address of Naeemeh Haddadi Esfahani at
pt_nhaddad@yahoo.com

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

Researchers working in academic and scientific institutions will have access to the data in the shortest possible time by making an official request from their respective faculty and providing documentation from the article in which they intend to use our data

Comments