

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of quadriceps neuromuscular electrical stimulation on pain scores, functional tests and quality of life of military personnel with partial anterior cruciate ligament tears

Protocol summary

Registration timing: **prospective**

Study aim

The effect of quadriceps neuromuscular electrical stimulation on pain scores, functional tests and quality of life in military personnel with partial anterior cruciate ligament tears

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 2 on 60 patients. Random blocks were used for randomization.

Registrant information

Name

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Name of organization / entity

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Settings and conduct

The non-blinded and randomized study will be conducted in the physical medicine clinic of Baqiyatullah Hospital. Sixty patients with partial rupture of the anterior cruciate ligament are included in the study, who are equally divided (30 people in each group) into intervention group of electrical nerve stimulation and the control group with routine treatment.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: partial tear of the anterior cruciate ligament of the knee, membership in military operational departments. Exclusion criteria: receiving physiotherapy 6 months ago, previous injury or history of surgery, history of chronic ankle instability.

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-01-20, 1402/10/30

Intervention groups

Intervention group: Quadriceps neuromuscular electrical stimulation; Control group: Without quadriceps neuromuscular electrical stimulation.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Pain, quality of life, walking speed.

Trial completion date

empty

General information

Scientific title

Investigating the effect of quadriceps neuromuscular electrical stimulation on pain scores, functional tests and quality of life of military personnel with partial anterior cruciate ligament tears

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231010059687N1**

Registration date: **2023-11-08, 1402/08/17**

Public title

Electrical neuromuscular stimulation of the quadriceps in subjects with partial anterior cruciate ligament tears

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Partial tear of the anterior cruciate ligament of the knee
Membership in military operational departments

Exclusion criteria:

Received physiotherapy 6 months ago
Previous injury or history of surgery
History of chronic ankle instability

Age

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

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to two intervention groups using randomized block method. For this purpose, blocks of size four are prepared, the name of the intervention is written on two sheets and the name of the comparison is written on the two other sheets. The sheets are piled up and placed in the container, and one sheet is pulled out for each patient without placing it. Then four sheets are returned to the container and this process is repeated until the sample volume is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah Hospital

Street address

Vanak sq

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.BMSU.BAQ.REC.1402.074

Health conditions studied

1

Description of health condition studied

Cruciate ligament tears

ICD-10 code

S83

ICD-10 code description

Dislocation and sprain of joints and ligaments of knee

Primary outcomes

1

Description

Pain

Timepoint

Before and after the intervention

Method of measurement

VAS score

2

Description

Measuring the quality of life

Timepoint

Before and after the intervention

Method of measurement

ACL QOL questionnaire

3

Description

Walking speed

Timepoint

Before and after the intervention

Method of measurement

10-meter walking test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: quadriceps neuromuscular electrical stimulation with biphasic symmetric pulse waveform (300 μ s phase deviation and 30 Hz frequency and maximum intensity of 100 mA on the vastus medialis muscle) for 10 sessions (number = 30) along with Infrared and Ultrasound to Duration of 10 minutes and exercises of the abductor, extensor muscles (3 sets and 20 repetitions), thigh, and Hamstring Curls exercise (3 sets and 30 repetitions).

Category

Rehabilitation

2**Description**

Control group: Infrared and Ultrasound for 10 minutes and exercises of abductor, extensor muscles (3 sets and 20 repetitions), thigh, and Hamstring Curls exercise (3 sets and 30 repetitions) (number = 30).

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

Full name of responsible person

Arman Mahmodi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

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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

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Arman Mahmodi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available