

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Does TENS help improve pain and function in the first phase of post ACL reconstruction rehabilitation?

Protocol summary

Summary

This double blind (exercise instructor and assessor) randomized clinical trial will be performed on seventy, 18 to 45, otherwise healthy subjects undergoing ACL reconstruction surgery after knee trauma . After surgery, patients will be randomly divided into two groups (receiving specific strengthening and stretching exercises for the knee plus TENS (100 hz, 100 microsecond, 35-40 minutes) or only exercise for two weeks) using sealed envelopes. . International Knee Documentation Committee (IKDC) questionnaire, range of motion (using goniometer) and VAS score will be evaluated for all patients after surgery (before rehabilitation program), after 2 and after 8-10 weeks from surgery to explore the possible additional effect of TENS on outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051521139N5**

Registration date: **2016-06-04, 1395/03/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

Name

Safoora Ebadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 175 7107

Email address

ebadi.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2016-10-20, 1395/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Does TENS help improve pain and function in the first phase of post ACL reconstruction rehabilitation?

Public title

The effect of TENS in the first phase of rehabilitation after ACL reconstruction surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: • Age: 18-45 • Having knee trauma • Meet the criteria for ACL reconstruction surgery • Not pregnant • No history of previous surgery in spine or lower extremities • No psychological problems • No systemic disease
Exclusion criteria: • Not willing to continue • Not being able to tolerate the intervention • Violation of any one of inclusion criterias

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

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

Double 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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

Tehran

Postal code

1449614535

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.IUMS.REC 1394.871410001

Health conditions studied**1****Description of health condition studied**

anterior cruciate ligament lesion

ICD-10 code

S83.5

ICD-10 code description

Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

Primary outcomes**1****Description**

Pain

Timepoint

before treatment-after 12 sessions of treatment- in 2

months followup

Method of measurement

visual analog scale

Secondary outcomes**1****Description**

function

Timepoint

before treatment -after 12 sessions of treatment- in 2months followup

Method of measurement

International Knee Documentation Committee (IKDC) questionnaire

Intervention groups**1****Description**

intervention: specific strengthening and stretching exercises for knee plus TENS : 100 hz, 100 microsecond,35-40 minutes ,12 sessions (2 weeks)

Category

Rehabilitation

2**Description**

control: specific strengthening and stretching exercises for knee for 2 weeks

Category

Rehabilitation

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

Firouzgar Hospital

Full name of responsible person

Dr. Safoora Ebadi

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

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

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Javad Ali Musavi

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences; Faculty of Medicine

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant Professor

Other areas of specialty/work

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

Postal code

Phone

+98 21 8214 1229

Fax

Email

ebadi.s@iums.ac.ir; e_safoora@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical sciences, Faculty of Medicine

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant professor, PhD Pt

Other areas of specialty/work

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

Postal code

Phone

+98 21 8214 1229

Fax

Email

ebadi.s@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical sciences

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant professor, PhD pt

Other areas of specialty/work

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

Postal code

Phone

+98 21 8214 1229

Fax

Email

ebadi.s@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty