

# 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

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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**

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**

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**Name of organization / entity**

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**Position**

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**Name of organization / entity**

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**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*