

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficiency of Action Potential Simulation (APS) therapy in compare to Transcutaneous Electrical Nerve Stimulation (TENS) in rehabilitation of knee osteoarthritis

Protocol summary

Summary

The aim of this study is determination of the best physical modality for pain relief in rehabilitation of knee osteoarthritis. Design of study is randomized and double blinded. The main inclusion criteria is mild or moderate knee osteoarthritis and the main exclusion criteria includes age under 50 years, patients suffering from rheumatologic disease, history of knee surgery and severe knee osteoarthritis. In this study 70 knee osteoarthritis patients will assign randomly to two groups, each group with 35 cases. Firs group will receive Action Potential Simulation (APS) in their physiotherapy protocol and second group will receive Transcutaneous Electrical Nerve Stimulation (TENS). The study will be conducted between 2012-01-01 and 2012-03-20. Main outcome is pain relief, which will be studied by the questionnaire VAS (Visual Analog Scale). The intervention includes 10 physiotherapy sessions. All patients (both groups) in physiotherapy sessions will receive the usual physical modalities equally. The only physical modality which is different in two groups is electrotherapy, one group will receive Action Potential Simulation (APS) and second group will receive Transcutaneous Electrical Nerve Stimulation (TENS). Time period for receiving electrotherapy in each session is 10 to 15 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112171292N2**

Registration date: **2012-01-06, 1390/10/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-06, 1390/10/16

Registrant information

Name

Vahideh Toopchizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 984113335625

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficiency of Action Potential Simulation (APS) therapy in compare to Transcutaneous Electrical Nerve Stimulation (TENS) in rehabilitation of knee osteoarthritis

Public title

Effectiveness of different physiotherapy protocols in rehabilitation of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Mild or moderate knee osteoarthritis based on American College of Rheumatology criteria
Exclusion criteria: Age under 50 years old; Rheumatologic disease; History of knee surgery; Lower limbs fracture with knee joint involvement; Severe knee osteoarthritis; Electrical implants like pacemaker; Heart conduction block disease; Epilepsy; Cancers; Pregnancy; Lower limbs thrombosis; Couldn't complete questioners for any reason; knee joint injection in previous 6 month; Balance control deficit; Neuropathy or sensory deficit; Skin breakdown in knee region

Age
From **50 years** old

Gender
Both

Phase
N/A

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
Tabriz University of Medical Sciences
Street address
Research ministry, Second central building, Tabriz University of Medical Sciences, Golgasht street
City
Tabriz
Postal code
Approval date
2011-11-21, 1390/08/30
Ethics committee reference number
9055

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M15.9
ICD-10 code description
Polyarthrosis, unspecified

Primary outcomes

1

Description
Pain relief
Timepoint
Before and after physioterapy
Method of measurement
Questioner

Secondary outcomes

1

Description
Improve performance
Timepoint
Before and after physioterapy
Method of measurement
Questioner

Intervention groups

1

Description
The intervention includes 10 physiotherapy sessions. All patients (both groups) in physiotherapy sessions will receive the usual physical modalities equally. The only physical modality which is different in two groups is electrotherapy, this group will receive Action Potential Simulation (APS). Time period for receiving electrotherapy in each session is 10 to 15 minutes.
Category
Rehabilitation

2

Description
The intervention includes 10 physiotherapy sessions. All patients (both groups) in physiotherapy sessions will receive the usual physical modalities equally. The only physical modality which is different in two groups is electrotherapy, this group will receive Transcutaneous Electrical Nerve Stimulation (TENS). Time period for receiving electrotherapy in each session is 10 to 15 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Dr Vahideh Toopchizadeh

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Tabriz University of Medical Sciences

Street address

Research ministry, second central building, Tabriz
University of Medical Sciences, Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Vahideh Toopchizadeh

Position

Physical Medicine and Rehabilitation

Other areas of specialty/work

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toopchi@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Vahideh Toopchizadeh

Position

Physical Medicine and Rehabilitation

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Vahideh Toopchizadeh

Position

Other areas of specialty/work

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Fax

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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