Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Vahideh Toopchizadeh
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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
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Sponsors / Funding sources

1

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

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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