Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Comparison of High intensity and Low intensity "High TENS" Effect on Pain relief and Functional activity Improvement in Patients with Knee Osteoarthritis

Protocol summary

Study aim

The comparison of high intensity and low intensity "High TENS" effect on pain relief and functional activity improvement in patients with knee osteoarthritis

Design

36 patients were divided randomly in 2 groups. Therapeutic protocol done on both groups was the same. Patients were under physiotherapy for 10 sessions, 3 times a week.

Settings and conduct

Patients were treated in physiotherapy clinic of Semnan University of medicine. Therapeutic protocol for patients includes applying electrical flow of high tens, ultrasound waves and heating modality. Also a practicing program was being prescribed for the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 50; Osteoarthritis of the knee joint diagnosed by Orthopedist or Rheumatologist; Feeling pain in knee in most days of the late month; Morning stiffness in knee joint for less than 30 minutes; Exclusion criteria: Other connective tissue and rheumatism diseases that can affect the knee; Acute neurological disorders or mental disorders; Injection of steroid inside the knee in the last 3 months; Having heart or other electrical implants; Having physiotherapy programs in the last 3 months.

Intervention groups

Both groups of attended patients in study, received high tens interference; in one with high intensity, in the other with low intensity.

Main outcome variables

Measuring the pain in the patient's knee will be conducted according to VAS standard and also evaluation of patient's functional activity levels according to WOMAC questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190108042292N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Cyrus Taghizadeh Delkhosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Comparison of High intensity and Low intensity "High TENS" Effect on Pain relief and Functional activity Improvement in Patients with Knee Osteoarthritis

Public title
The Effect of High TENS Intensity on Knee Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 50 Osteoarthritis of the knee joint diagnosed by Orthopedist or Rheumatologist Feeling pain in knee in most days of the last month Morning stiffness in knee joint for less than 30 minutes

Exclusion criteria:
Other connective tissue and rheumatism diseases that can affect the knee Acute neurological disorders or mental disorders Injection of steroid inside the knee in the last 3 months Operation in knee joint Having heart or other electrical implants Having physiotherapic programs in the last 3 months

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients will be divided in two groups with same numbers by simple random sampling. Each patient will be placed in a group by flipping a coin, so that if one of the groups was filled sooner, other patients will be taking place in the other group

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 Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
Semnan

Province
Semnan

Postal code
3519899951

Approval date
2018-03-14, 1396/12/23

Ethics committee reference number
IR.SEMUMS.REC.1396.265

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain Intensity in VAS

Timepoint
First Session, Fifth Session, Tenth Session

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 sessions of physiotherapy (3 sessions per week) including the modalities below:-20 minutes of high TENS electrical flow, with high voltage, 100Hz frequency and 50μs pals duration on the knee -Ultrasound waves with 1MHz frequency and 0.8 watt per square centimeters insolation on inner and outer surface of the knee for 6 minutes -Applying heat by infrared bulbs on knee for 15 minutes-Stretching exercises for the muscles around the knee

Category
Rehabilitation

2

Description
Intervention group: 10 sessions of physiotherapy (3 sessions per week) including the modalities below:-20 minutes of high TENS electrical flow, with low voltage,

100Hz frequency and 50µs pals duration on the knee - Ultrasound waves with 1MHz frequency and 0.8 watt per square centimeters insolation on inner and outer surface of the knee for 6 minutes -Applying heat by infrared bulbs on knee for 15 minutes -Stretching exercises for the muscles around the knee

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn Sina Rehabilitation Clinic

Full name of responsible person

Mohsen Pakdaman

Street address

Ebn Sina Clinic, 17 Shahrivar Blvd, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaie

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Syrus Taghizadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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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
No additional 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