

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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

+98 23 3365 4180

##### Email address

cyrustaghizadeh@semums.ac.ir

##### 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 physiotherapeutic 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 50 $\mu$ s pulse 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

###### City

Semnan

###### Province

Semnan

###### Postal code

3519899951

###### Phone

+98 23 3332 2332

###### Email

mohsen.pkdmn.1376@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Semnan University of Medical Sciences

###### Full name of responsible person

Dr Parviz Kokhaie

###### Street address

Semnan University of Medical Sciences, Basij Blvd,  
Semnan

###### City

Semnan

###### Province

Semnan

###### Postal code

3514799442

###### Phone

+98 23 3345 1336

###### Email

p\_kokha@yahoo.com

###### 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

##### Street address

School of Rehabilitation, Semnan University of  
Medical Sciences, Damghan Rd, Swmnan

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##### Email

cyrustaghizadeh@semums.ac.ir

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Dr Syrus Tghizadeh

##### Position

Assistant Professor

##### Latest degree

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##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Syrus Taghizadeh

**Position**

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**Postal code**

## 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