

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The influence of high voltage pulse current on pain, effusion and range of motion in subjects with anterior knee pain

Protocol summary

Study aim

- To determine and compare the mean pain, effusion and range of motion in patients with anterior knee pain before treatment, after 5 sessions treatment, after 10 sessions treatments and after one month follow-up in high voltage pulse current and control groups.

Design

Randomized controlled clinical trial with factorial groups and double blinded

Settings and conduct

The rationale for this research is to determine the effects of high voltage pulse current on pain, range of motion and effusion in patients with anterior knee pain. This will be done in Poursina Hospital and neither patients nor examiner know the grouping and treatment procedures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 16 to 60 years. Anterior knee pain and effusion diagnosis: According to orthopedic physician assessment; Exclusion criteria: Patients with anterior knee pain without effusion. Patients with arthrosis grade III and IV according to X-Ray. Patients with tibia, patella, femur and fibula fractures. Patients with history of femur and other bones surgery, or meniscus and cruciate ligaments and tendon surgery. Patients with complete soft tissue tear such as meniscus and cruciate ligaments. Patients with referral pain from lumbar or hip and local infections. Addict or pregnant individuals. Patients that took part in physiotherapy program about during 2 weeks ago. Patients with history of rheumatoid diseases such as rheumatoid arthritis.

Intervention groups

Control group receive routine physical therapy treatments and intervention group receive routine physical therapy as well as high voltage pulse current

Main outcome variables

Knee pain Knee effusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N3**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **prospective**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Kamran Ezzati

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0099

Email address

kamranezzati@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The influence of high voltage pulse current on pain, effusion and range of motion in subjects with anterior knee pain

Public title

The effects of high voltage pulse current on pain, effusion and range of motion in subjects with anterior knee pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Anterior knee pain and effusion diagnosis: According to orthopedic physician assessment The patients with knee effusion affected by patellofemoral pain syndrome or osteoarthritis grade I and II without complete tear of soft tissues.

Exclusion criteria:

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The grouping method will be Permuted block randomization . So, blocks of 10 people including 5 participants in the intervention group and 5 participants in the control group are allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The examiner won't know anything about the kind of treatment. The Patients and therapists will also not know anything about grouping and kind of interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی گیلان

Street address

5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

City

Rasht

Province

Guilan

Postal code

۴۱۹۳۷۱۳۱۹۴

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.GUMS.REC.1397.3

Health conditions studied

1

Description of health condition studied

Anterior knee pain

ICD-10 code

M19.0

ICD-10 code description

Arthrosis

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Effusion score

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

Tape

2

Description

Range of Motion

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

Goniometer

Intervention groups

1

Description

Control group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the shoulder of the individual. The patient will feel mild heat. 2- Treatment with transcutaneous electrical nerve stimulation(TENS) type brief for 20 minutes. In this method, four electrodes on the sides of the knee will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily.

Category

Rehabilitation

2

Description

Intervention group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the shoulder of the individual. The patient will feel mild heat. 2- Treatment with TENS type brief for 20 minutes. In this method, four electrodes on the sides of the shoulder will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily. 4. high voltage pulse current: In this study, Four electrodes from proximal to distal of the knee joint will be placed with intermittent polarity. The treatment time will be 20 min for each patient. Minimal scene of electrical stimulation is perceived by the patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان پورسینا

Full name of responsible person

کامران عزتی

Street address

Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht

City

Rasht

Province

Guilan

Postal code

4193731943

Phone

+98 13 3332 2444

Email

Ez_kamran@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Shadman nemati

Street address

Deputy of Research, Opposite to Azodi Stadium, Namjoo St, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

9131293466

Phone

+98 13 3333 5821

Email

Research@gums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Guilan 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

Guilan University of Medical Sciences, Deputy of Research

Full name of responsible person

Sosan Komaei

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Medical Education

Street address

Deputy of Research, Opposite to Azodi Stadium, Namjoo St, Rasht, Iran

City

Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3336 2639
Email
Research@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Kamran Ezzati
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Central Office of Guilan University of Medical Sciences, Parastar St., Rasht, I.R. Iran
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3369 0099
Email
kamranezzati@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Kamran Ezzati
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work

Physiotherapy
Street address
Central Office of Guilan University of Medical Sciences, Parastar St., Rasht, I.R. Iran
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3369 0099
Email
kamranezzati@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sharing is done after the end of the study. The total potential data can be shared after unidentifications of individuals.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers working in universities

Under which criteria data/document could be used

Researchers working in universities

From where data/document is obtainable

Address: Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht. Ez_kamran@yahoo.com

What processes are involved for a request to access data/document

A written request for data from the relevant university with the name and academic degree of the researcher

Comments