

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Action Potential Simulation and Low Level LASER in Reducing Pain and Improving Function of the Knee: A Randomized Controlled Trial of Women with Knee Osteoarthritis

Protocol summary

Summary

This study aimed to compare the effects of action potential simulation with low level LASER in reducing pain and improving function of women with knee osteoarthritis. This single-blind, randomized clinical trial was carried out in Zahedan University of Medical Sciences, in 2009. Thirty patients with knee Osteoarthritis were recruited through simple non-probability sampling. Patients were selected based on following inclusion criteria: Age between 14 and 40, having knee pain according to Altman's classification, lack of regular exercise (non-professional or professional) over the past 10 years, not regular or irregular (5 times per week) of analgesics and steroidal and non-steroidal anti-inflammatory drugs within 2 months prior to study entry. Patients were excluded if they had insufficient treatment, using other therapeutic modalities during the study, trauma, doing surgery during the study, exacerbation of symptoms following the intervention, patients who have had a history of knee surgery, intra-articular injections in the past 6 months; and lower extremity fracture in last 3 months. Patients were randomly assigned to either a low-level LASER group (N=15) or an action potential simulation group (APS) (N=15). In LASER group, a low-level Ga-As LASER was applied with 5 KHz frequency, a 100 mW point probe (average power), wavelength 905 nm, pulse duration 200 ns, 9 J/cm² dosages per minute, for 6 minutes per session. In action potential simulation group, action potential simulation was applied with intensity of 1mA, 150 Hz frequency, for 16 minutes per session. Both groups received exercises including strengthening of quadriceps, adductors of the hip, and stretching of iliotibial band, buttock, calf and hamstring muscles and hot pack. A 16-session treatment program, during 4 weeks, 4 sessions per week was performed for both groups. Before and after intervention, we measured pain

through Visual Analog Scale (VAS) (ordinal), function with Knee and Osteoarthritis Outcome Score (KOOS), and range of knee flexion with goniometer (degree), stiffness, pain and physical function with Western Ontario and McMaster Universities Index (WOMAC) (Ordinal) and atrophy and swelling with tape measure (centimeter).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109231675N9**

Registration date: **2011-10-31, 1390/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-31, 1390/08/09

Registrant information

Name

Asghar Akbari

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Zahedan University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01
Expected recruitment end date
 2009-12-22, 1388/10/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effect of Action Potential Simulation and Low Level LASER in Reducing Pain and Improving Function of the Knee: A Randomized Controlled Trial of Women with Knee Osteoarthritis

Public title
 The effect of Action Potential Simulation and Low Level LASER in Reducing Pain and Improving Function of the Knee: A Randomized Controlled Trial of Women with Knee Osteoarthritis

Purpose
 Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Age between 14 and 40; Having knee pain according to Altman's classification; Lack of regular exercise (non-professional or professional) over the past 10 years; Not regular or irregular (5 times per week) of analgesics and steroidal and nonsteroidal anti-inflammatory drugs within 2 months prior to study entry. Exclusion criteria: Insufficient treatment; Using other therapeutic modalities during the study; Trauma; Doing surgery during the study; Exacerbation of symptoms following the intervention; Patients who have had a history of knee surgery; Intra-articular injections in the past 6 months; and Lower extremity fracture in last 3 months.

Age
 From **40 years** old to **65 years** old

Gender
 Female

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

1

Registry name
 No registration
Secondary trial Id
 No trial id
Registration date
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of University of Sistan and Baluchestan
Street address
 Daneshgah Blvd., University of Sistan and Baluchestan
City
 Zahedan
Postal code
 987-98155
Approval date
 2011-10-22, 1390/07/30
Ethics committee reference number
 902.2.231

Health conditions studied

1

Description of health condition studied
 Knee Osteoarthritis
ICD-10 code
 M17.0, M17
ICD-10 code description
 Primary gonarthrosis, bilateral and Other primary gonarthrosis

Primary outcomes

1

Description
 Knee pain
Timepoint
 Before intervention, 4 weeks after intervention
Method of measurement
 Visual Analogue Scale

2

Description
 Knee function
Timepoint
 Before intervention, 4 weeks after intervention
Method of measurement
 Knee and Osteoarthritis Outcome Score (KOOS)

3

Description

Range of knee flexion

Timepoint

Before intervention, 4 weeks after intervention

Method of measurement

Goniometer

4

Description

Stiffness, pain and physical function

Timepoint

Before intervention, 4 weeks after intervention

Method of measurement

Western Ontario and McMaster Universities Index (WOMAC)

5

Description

Atrophy

Timepoint

Before intervention, 4 weeks after intervention

Method of measurement

Tape measure

6

Description

Swelling

Timepoint

Before intervention, 4 weeks after intervention

Method of measurement

Tape measure

Secondary outcomes

empty

Intervention groups

1

Description

LASER Group: A low-level Ga-As LASER was applied with 5 KHz frequency, a 100 mW point probe (average power), wavelength 905 nm, pulse duration 200 ns, 9 J/cm² dosages per minute, for 6 minutes per session. In addition, this group received hot pack and exercises including strengthening of quadriceps, adductors of the hip, and stretching of iliotibial band, buttock, calf and hamstring muscles. A 16 session's treatment program which lasted 4 weeks and 4 sessions per week was performed.

Category

Rehabilitation

2

Description

Action Potential Simulation Group: We applied Action

Potential Simulation with intensity of 1mA, 150 Hz frequency, for 16 minutes per session. This group received hot pack and exercises including strengthening of quadriceps, adductors of the hip, and stretching of iliotibial band, buttock, calf and hamstring muscles. A 16 session's treatment program which lasted 4 weeks and 4 sessions per week was performed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Razmejo-Moghadam Physiotherapy Clinic

Full name of responsible person

Dr. Asghar Akbari

Street address

Dept. of Physiotherapy, School of Rehabilitation Sciences, Razmejo-Moghadam Laboratory, Ayatoallah Kafami St.

City

Zahedan

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for Research of Zahedan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Mahmoudzadeh Sagheb

Street address

Deputy Of Research, Zahedan University of Medical Sciences, Jannat Blvd., Dr. Hesabi Sq., Zahedan.

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research of Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Asghar Akbari

Position

Ph.D in Physiotherapy, Head of Dept. of Physiotherapy.

Other areas of specialty/work**Street address**

Dept. of Physiotherapy, School of Rehabilitation Sciences, Razmejo-Moghadam Laboratory, Ayatoallah Kafami St., Zahedan.

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Position

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Other areas of specialty/work**Street address**

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Full name of responsible person

Dr. Asghar Akbari

Position

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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