Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Osteoarthrosis

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 osteoarthrosis. This single-blind, randomized clinical trial was carried out in Zahedan University of Medical Sciences, in 2009. Thirty patients with knee Osteoarthrosis 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

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Zahedan University of Medical Sciences
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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 Osteoarthrosis

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 Osteoarthrosis

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 Commitee 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 Osteoarthrosis

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 0f 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

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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