Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

effect of Augmented High Intensity Laser Therapy (HILT) to Electrical Stimulation (NMES) and Exercise Therapy on Muscle Strength, Pain and Function in Patients with Knee Osteoarthritis Grade II and III: a randomized controlled trial

Protocol summary

Study aim
Investigation the effects of augmented high intensity LASER therapy with electrical stimulation and exercise therapy on muscle strength and pain and function in patients with knee osteoarthritis grade II and III : A Randomized Clinical Trial

Design
Clinical trial with control group, Two arm parallel group,double blind with blinded outcome evaluator and participants, simple randomaised

Settings and conduct
Participants after having inclusion criteria for entry to test randomly simple in two groups control group: Placebo high intensity LASER with neuromuscular electrical stimulation and exercise therapy Treatment group: High intensity LASER with neuromuscular electrical stimulation and exercise therapy Ten treatment sessions were done for participants. Assessment of participants done before and after treatment, session10, A month and a half after treatmen. Assessment of pain performed with visual analog scale, strength of quadriceps muscle with manual dynamometer and function with Western Ontario and McMaster Universities Arthritis Index.This is a double-blind study with blinded outcome evaluator and participants.All stages of study were conducted at Ahwaz Jundishapour University of Medical Sciences.

Participants/Inclusion and exclusion criteria
inclusion criteria: Radiographic evidence of knee and knee osteoarthritis, Knee pain for at least three months, physiotherapy and injection within the last six months. no pacemaker, cardiovascular disease, knee arthroplasty, tumor and deep vein thrombosis. Exclusion criteria: No willing the samples to continue the treatment process

Intervention groups
control group: Placebo high intensity LASER with neuromuscular electrical stimulation and exercise therapy Treatment group: High intensity LASER with neuromuscular electrical stimulation and exercise therapy

Main outcome variables
Pain Strength of Quadriceps muscle function

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20181024041442N1**
Registration date: **2019-02-10, 1397/11/21**
Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**
Update count: **0**

Registration date
2019-02-10, 1397/11/21

Registrant information

Name
Shahin Goharpay

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3374 3101

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01
Expected recruitment end date
2018-12-21, 1397/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
effect of Augmented High Intensity Laser Therapy (HILT) to Electrical Stimulation (NMES) and Exercise Therapy on Muscle Strength, Pain and Function in Patients with Knee Osteoarthritis Grade II and III: a randomized controlled trial

Public title
effect of high intensity laser therapy on knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Radiographic evidence of knee osteoarthritis grade II and III according to the Kellgren-Lawrence classification and based on American College of Rheumatology (ACR) criteria knee pain for at least 3 months. without application of injection or physiotherapy during the last six months
Exclusion criteria:
Not willing the samples to continue the treatment process
Age
From **50 years** old to **75 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomized Individual Use the random numbers table People first enter each number next members were selected with 5 spacing
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants did not know the presence of the control group. Also, they did not know what treatment group they were supposed to be. Assessing the outcome without knowing the types of groups and types of treatments evaluated the participants before and after treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahwaz Jundishapur University of Medical Sciences
Street address
Depatment of Physical Therapy, School of Rehabilitation Sciences, Ahwaz Jundishapur University of Medical Sciences, Ahwaz, Iran
City
Ahwaz
Province
Khouzestan
Postal code
61357-33133'
Approval date
2018-06-30, 1397/04/09
Ethics committee reference number
IR.AJUMS.REC.1397.267

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis Grade II and III
ICD-10 code
M15.9
ICD-10 code description
Generalized Osteoarthritis NOS

Primary outcomes

1

Description
pain
Timepoint
before treatment, session10, A month and a half after treatment
Method of measurement
The visual Analog scale of pain. score is from 0 to 100 mm. 100 max pain and 0 painless state.

2

Description
strength of quadriceps
Timepoint
before treatment, session10, A month and a half after

treatment

Method of measurement

manual dynamometer

Secondary outcomes

1

Description

function

Timepoint

before treatment, session10, A month and a half after treatment

Method of measurement

Western Ontario and McMaster Universities Arthritis Index

Intervention groups

1

Description

Intervention group includes high intensity laser with neromuscular electrical simulator and exercise therapy

Category

Treatment - Devices

2

Description

Control group includes neromuscular electrical simulator and exercise therapy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvar Jondishapour University of Medical Sciences

Full name of responsible person

Dr. Shahin Goharpey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badvi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Shahin Goharpey

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available