

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 randomised

##### 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, session 10, A month and a half after treatment. 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)

##### Phone

+98 61 3374 3101

##### Email address

goharpay-sh@ajums.ac.ir

##### 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**

Department 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

**Street address**

Golestan Blvd

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3374 3505

**Email**

shgoharpey@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Badvi

**Street address**

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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**

Ahwaz 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**

Ahwaz 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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## Person responsible for scientific inquiries

### Contact

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Ahvaz University of Medical Sciences

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## Person responsible for updating data

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**Fax****Email**

goharpay-sh@ajums.ac.ir

## 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