Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of Mechanical Traction and Simultaneous High Intensity Laser Irradiation Effects on Pain, Lower Extremity Muscles Activity, and Functional Balance in People with Knee Osteoarthritis

Protocol summary

Study aim
Evaluation of mechanical traction and simultaneous high intensity laser irradiation effects on pain, lower extremity muscles activity, and functional balance in people with knee osteoarthritis

Design
Randomized clinical trial with blinded evaluator on 28 patients, with 2 parallel intervention groups. Randomization was computerized with concealed randomization sequence carried out by Excel software.

Settings and conduct
This single blind study will be conducted in the biomechanics laboratory of Tarbiat Modares University with a blind assessor. The random allocation list will be created by a person who is not involved in the evaluation and treatment using Excel 2016 software. Concealment of random allocation will be based on opaque, thick, sealed envelopes numbered consecutively

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with grade 3 tibiofemoral osteoarthritis, 25≤BMI<30 Exclusion criteria: Other rheumatological conditions, recent fracture around the knee, lower limb deformity, osteoporosis, bone tumors, history of cancer, presence of bone implant, infection

Intervention groups
Patients are randomly assigned to two groups: The first group will be treated with high intensity laser, and the second group will receive continuous mechanical traction in addition to the high intensity laser. High intensity laser will be used by following parameters: Wavelengths of 660, 800, 906 and 970 nm, Variable maximum power up to 20 watts and average power of 9 watts 2277 joules of total energy, Frequency of the device (10-20000 Hz) and the total duration of the treatment is 4 minutes and 13 seconds. For group 2 the traction force is applied continuously and equal to 10% of the patient's body weight for 20 minutes through an adjustable weight cuff that will be tied around the patient's distal leg in sitting position with knee in 90 degree flexion.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230603058371N1**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **prospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date
2023-06-07, 1402/03/17

Registrant information

Name
Pardis Norouzi

Name of organization / entity
Tarbiat Modares University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-06, 1402/04/15

Expected recruitment end date
2025-03-18, 1403/12/28

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Mechanical Traction and Simultaneous High Intensity Laser Irradiation Effects on Pain, Lower Extremity Muscles Activity, and Functional Balance in People with Knee Osteoarthritis

Public title
Evaluation of Mechanical Traction and Simultaneous High Intensity Laser Irradiation Effects on Pain, Lower Extremity Muscles Activity, and Functional Balance in People with Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People who are symptomatically and radiologically suffering from grade 3 tibiofemoral osteoarthritis based on the Kellgren-Lawrence radiological grading scale and meet the criteria of the American College of Rheumatology Moderate pain range (score 45-74 on the 100 mm VAS scale) Body mass index 25≤BMI<30 Lower limb muscle strength equal to or greater than grade 4 based on Kendall and Daniel
Exclusion criteria:
Other rheumatological conditions, recent fracture around the knee, lower limb deformity, osteoporosis, bone tumors Varus knee deformity more than 5 degrees, valgus more than 15 degrees History of cancer Presence of bone implant People with a history of surgery on the knee joint Infection Open wounds or skin disease around the knee joint Injections or physiotherapy on the knee in the last three months, using steroidal or non-steroidal anti-inflammatory drugs in the last 15 days Other causes of pain in the lower limbs (such as polyneuropathy, restless leg syndrome, fibromyalgia, hip joint pathology, spine root compression, central nervous system diseases), mental disorders
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation list will be created by a person who is not involved in the evaluation and treatment using Excel 2016 software in such a way that in a two-column table, the right column contains the number of all participants in the order of entry and the left column contains the random letters A (high intensity laser group) and B (high intensity laser and mechanical traction group) which determines the order of random placement of patients in one of the two intervention groups. Concealment of random allocation will be based on opaque, thick, sealed envelopes numbered consecutively. The numbered envelopes with consecutive numbers according to the order of subjects entering the study, determine which of the treatment groups each patient will be placed in.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor and the therapist are two different people, and the assessor is not aware of the placement of the patients in the treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares Faculty of Medical Sciences
Street address
Jalal Al Ahmad Ave
City
Tehran
Province
Tehran
Postal code
14115111
Approval date
2023-05-29, 1402/03/08
Ethics committee reference number
IR.MODARES.REC.1402.036

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain
Timepoint
Before treatment, 48 hours after 10 treatment sessions
Method of measurement
100 millimeter visual analog scale

Secondary outcomes

1

Description
Knee function
Timepoint
Before treatment, 48 hours after 10 treatment sessions
Method of measurement
WOMAC questionnaire

2

Description
The electrical activity of lower extremity muscles includes: Mean root mean square, Median root mean square, Median frequency, Co-contraction index
Timepoint
Before treatment, 48 hours after 10 treatment sessions
Method of measurement
Surface Electromyography signal analysis

3

Description
Functional balance index include: Center of pressure sway velocity, Rising index, Weight transfer time, Mean absolute error, Standard deviation of absolute error, Root mean square error, Area, Normalized error
Timepoint
Before treatment, 48 hours after 10 treatment sessions
Method of measurement
Kistler MARS device data analysis

Intervention groups

1

Description
Intervention group: Group 1:The first group is treated with high intensity laser. High intensity laser is applied using the American K LASER device with the following parameters: Wavelengths of 660, 800, 906 and 970 nm, variable maximum power up to 20 watts and average power of 9 watts, 2277 joules of total energy, during 11 phases of 23 seconds (the first and last phase are continuous wave and the other phases are pulse), frequency of the device (10-20000 Hz) and the total duration of the treatment is 4 minutes and 13 seconds. continuous circular movements of the probe on the anterior, medial and external surface of the knee joint line between the epicondyles of the femur and tibia (2000 J) and around the patella (277 J) will be applied. Patients will receive 10 treatment sessions in two weeks.
Category
Treatment - Devices

2

Description
Intervention group: For group 2, at the same time as applying a high intensity laser with the same parameters as group 1, the continuous traction force is applied equal to 10% of the patient's body weight for 20 minutes through an adjustable weight cuff around the patient's distal leg in a sitting position with the knee in 90 degree flexion. Patients will receive 10 treatment sessions in two weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tarbiat Modares University
Full name of responsible person
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Sponsors / Funding sources

1

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Email
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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
Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
Pardis Norouzi
Position
Ph.D student
Latest degree
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Person responsible for updating data

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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