Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of low-level laser therapy on muscle performance of young adults

Protocol summary

Study aim
Investigation of the effect of low-level laser on muscle performance in people 20 to 35 years old

Design
A double-blinded, placebo-controlled, randomized clinical trial

Settings and conduct
Place of study performance: Sports medicine ward, Taleghani Hospital, Shahid Beheshti University of Medical Sciences Study protocol: 50 patients referring to the sports medicine ward from April 2018 to March 2019 who met the inclusion criteria, were included after explaining the study protocol and signing informed consent. The study was double-blinded. The participant didn’t know in which group is settled and the operator couldn't differentiate between active and placebo laser.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 20-35, No history of regular exercise during the past 3 months, No history of professional exercise throughout life Exclusion criteria: musculoskeletal disorders prohibiting the use of a treadmill or weight, Consuming any drug or supplements, History of Quadriceps femoris or Hamstring muscles injury

Intervention groups
Treatment group: The participants that in the second session, before the exercise, received one session of the active laser at 810 nm wavelength and 60Hz frequency on 3 points of rectus femoris muscle, 30 seconds on each point (the laser device brand MPTC, model LMPT2000, made in Iran). The distance between the Anterior Superior Iliac Spine to the upper border of the Patella was divided into 3 equal regions and the middle point of every region was considered as an irradiation point. Control group: The participants that in the second session, before the exercise, received a laser with the probe off with the same protocol

Main outcome variables
Number of weight repetitions, the blood level of lactate, Fatigue(measured subjectively by the Rating of Perceived Scale from 6 to 20), Muscle pain (measured subjectively by scoring from 1 to 10)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047097N1**
Registration date: **2020-06-08, 1399/03/19**
Registration timing: **retrospective**

Last update: **2020-06-08, 1399/03/19**
Update count: **0**

Registration date
2020-06-08, 1399/03/19

Registrant information

Name
Nina Hazegh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3263 4143

Email address
h.anahita64@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-02, 1397/01/13

Expected recruitment end date
2019-03-16, 1397/12/25

Actual recruitment start date
2018-04-07, 1397/01/18

Actual recruitment end date
2018-12-17, 1397/09/26

Trial completion date
2018-12-17, 1397/09/26

Scientific title
Effect of low-level laser therapy on muscle performance of young adults

Public title
Effect of low-level laser therapy on muscle performance of young adults

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age in the range of 20-35 Being sedentary (no history of regular exercise during the past 3 months) No history of professional sport during the lifetime

Exclusion criteria:
Any musculoskeletal disorder prohibiting the use of a treadmill or weight Consuming any drug or supplements Previous history of injury to Quadriceps femoris or Hamstring muscles

Age
From **20 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
To minimize the risk of selection bias, block randomization was performed. The participants, according to their Body Mass Index or BMI, were divided into two subgroups of BMI less than 25 (22 participants) and BMI equal to 25 or more (28 participants). Randomization was carried out in each subgroup separately, with a block size of 4. 2 cards of A and 2 cards of B were shuffled and randomly put together and the operator of the randomization, according to the order that the cards were arranged, assigned the participants to groups A or B. The participant who had received card A, was placed in group A and received a real laser, whereas the participant who had received card B, was placed in group B and received a placebo. All of the randomization steps were carried out by the trial operators. The participants and the operators of randomization didn't know to which group A and B cards belong.

Blinding (investigator's opinion)
Double blinded

Blinding description
To avoid performance bias, double-blinding was done; meaning that the participants didn't know whether they were in the real laser or the placebo group and the laser therapy operator was unable to differentiate between active and placebo laser. The laser device was programmed by a nurse who was not in contact with the participants. Then a second operator who was blinded to the allocation of the subjects applied the phototherapy. The signals and sounds of the device in on and off mode were completely similar and the operator couldn't differentiate whether it is on or off. So, both participants and operators were blinded to the type of treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Third floor, Medicine faculty, Kudakyar St., Shahid Shahriary Sq., Shahid Chamran highway, Tehran

City
Tehran

Province
Tehran

Postal code
1985717434

Approval date
2018-07-17, 1397/04/26

Ethics committee reference number
IR.SBMU.MSP.REC.1397.459

Health conditions studied

1

Description of health condition studied
Rehabilitation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Level of the blood lactate

Timepoint
At the beginning of the study 3 days before the intervention and in the second session 20 minutes after the intervention.

Method of measurement
Lactometer brand ECF (made in Italy) and brand Sensal No 74 lactometer kit (made in China), using a fingertip blood sample. The blood sample was collected by puncturing the fingertip using a lancet brand Ava (made

in Iran).

2

Description
Number of knee extensions with a 10 kg weight
Timepoint
At the beginning of the study 3 days before the intervention and in the second session 5 minutes after the intervention
Method of measurement
Counting the number of complete knee extensions

Secondary outcomes

1

Description
Fatigue
Timepoint
At the beginning of the study 3 days before the intervention and 20 minutes after the intervention in the second session
Method of measurement
Scoring subjectively by the RPE (Rating of Perceived Exertion) scale, from 6 (minimum fatigue) to 20 (exhaustion)

2

Description
Muscle soreness
Timepoint
2 days before the intervention (24 hours after the first session exercise) and 24 hours after the intervention
Method of measurement
Scoring subjectively from 1 (the least pain) to 10 (the maximum pain)

Intervention groups

1

Description
Intervention group: The participants settled in group A due to the block randomization and in the second session, before the exercise, receive one session of the real laser at 810 nm wavelength, 60mW power, and 60Hz frequency for 30 seconds on 3 points of rectus femoris muscle, 30 seconds on each point. (Laser device brand MPTC, model LMPT2000, made in Iran). To find the points, the distance between the Anterior Superior Iliac Spine (ASIS) to the upper border of the patella was divided into 3 equal regions and the middle point of every region was considered as an irradiation point.
Category
Rehabilitation

2

Description
Control group: The participants settled in group B due to the block randomization and in the second session, before the exercise, received the placebo laser (with probe off) on 3 points of rectus femoris muscle, 30 seconds on each point. (Laser device brand MPTC, model LMPT2000, made in Iran). To find the points, the distance between the Anterior Superior Iliac Spine (ASIS) to the upper border of the patella was divided into 3 equal regions and the middle point of every region was considered as an irradiation point.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani hospital
Full name of responsible person
Nina Hazegh
Street address
Ayatollah Taleghni hospital, Shahid Arabi st., Yaman st., Shahid Chamran highway
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Phone
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Email
taleghani@sbmu.ac.ir
Web page address
https://taleghani.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Beside Ayatollah Taleghani hospital, Shahid Arabi st., Yaman st., Shahid Chamran highway, Tehran, Iran
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Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Web page address
http://sbmu.ac.ir
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nina Hazegh

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Specialist physician

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Person responsible for updating data

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Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
Yes - There is 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

Title and more details about the data/document
Using the data is allowed after the participants are non-recognizable

When the data will become available and for how

long

Beginning the data access 6 months after the results are published

To whom data/document is available

All researchers in university associations

Under which criteria data/document could be used

Data analysis is allowed for use in meta-analyses and clinical review studies

From where data/document is obtainable

for accessing the data please send an e-mail to the address h.anahita64@yahoo.com Dr. Nina Hazegh. Name and the telephone number, the association, posting address, e-mail of the person who has requested for the data is necessary.

What processes are involved for a request to access data/document

after receiving the request and recognizing the identity of the person who has sent the request, the data will be sent in a week

Comments