

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 Taleghani hospital, Shahid Arabi st., Yaman st., Shahid Chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 23031

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

City

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
Street address
No7., Masud deadend, Golestan deadend, Jeishir St.,
3rd Moshtagh St.
City
Isfahan
Province
Isfahan
Postal code
8158161543
Phone
098 31 32634143
Email
h.anahita64@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nina Hazegh
Position
Specialist physician
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
No 7 masud dead end, Golestan avenue, Sarvestan
street, Jeishir street, 3rd Moshtagh street

City
Isfahan
Province
Isfahan
Postal code
8158161543
Phone
+98 31 3263 4143
Fax
Email
h.anahita64@yahoo.com

Person responsible for updating data

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
Street address
No7., Masud deadend, Golestan deadend, Jeishir St.,
3rd Moshtagh St.
City
Isfahan
Province
Isfahan
Postal code
8158161543
Phone
0098 31 2634143
Email
h.anahita64@yahoo.com

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