Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of low-level laser in patients with Grade 2 and 3 fatty liver with increased liver enzymes

Protocol summary

Study aim

The purpose of this study was to evaluate the effectiveness of low-power laser in treating fatty liver with the aim of providing easier and more effective treatment.

Design

In a randomized, double blinded clinical trial, 60 patients with Grade 2 and 3 fatty liver with elevated liver enzymes confirmed by sonography were selected from 30 to 50 years old and divided into two groups: low-power laser and control group.

Settings and conduct

Patients in Shohada Tajrish hospital with Grade 2 and 3 fatty liver and elevated liver enzymes confirmed by sonography were selected in 30-50 years old patients and divided into two groups of low-level laser and control group. All patients were randomly assigned based on random numbers into two groups. The group assigned to the subject is buried in dark envelopes. The envelope will be opened by a doctor only after the initial assessment of each person, and the patient and the clinical evaluator of his treatment group won't be informed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Grade 2 and 3 fatty liver with increased liver enzymes; age 30 to 50 years; Complete satisfaction to participate in the study and completion of treatment and follow up; Exclusion criteria: Patients with diabetes; Pregnant and lactating; Metabolic syndrome; Hyperlipidemia and Hypercholesterolemia; taking any medication in the last month; hepatitis; cardiovascular patients; hypertension; hyper and hypothyroidism; fibroma and polycystic ovary; hormonal disorders; age under 30 and over 50;

Intervention groups

Treatment group: low-level laser with a wavelength of 830 nm, a power of 35 mW, on four points (right upper, right lower, upper left, lower left of liver or four lobes of the liver) with different jules per patient (depth of the liver is measured in the primary ultrasound and from the energy divided by surface formula will be achieved) 3 times per week for 12 sessions. Control group: Sham laser (silent laser) without output for blindness at the same points. All variables, including duration of radiation and the number of treatment sessions in the control group, will be exactly the same as the case group, and the treatment will be given by the same physician in this group.

Main outcome variables

Liver enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N18**
Registration date: **2018-01-08, 1396/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**
Update count: **1**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name
Mohammadreza Razaghi
Name of organization / entity
Laser application in medical sciences research center
Country
Iran (Islamic Republic of)
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+98 21 2271 8021
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-08-23, 1397/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of low-level laser in patients with Grade 2 and 3 fatty liver with increased liver enzymes

Public title
Evaluation of the effect of Laser in Fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fatty liver grade2 and 3 with increased liver enzymes Age 30 to 50 years Complete satisfaction to participate in the study and completion of the therapeutic and follow up process
Exclusion criteria:
Diabetes Pregnant and lactating Metabolic syndrome Hyperlipidemia and hypercholesterolemia Age under 30 and over 50 years Taking any medication in a recent month hepatitis Cardiovascular patients Hypertension Hyperthyroidism and Hypothyroidism Fibroma and polycystic ovaries Hormonal disorders
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups with simple and individual randomized based on randomized 1: 1 random numbers. The group assigned to the subject is buried in dark envelopes. The envelope will be opened by a doctor only after the initial assessment of each person, and the patient and the clinical evaluator won't be informed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the clinical evaluator will not be aware of the treatment group.
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
Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran
City
Tehran
Province
Tehran
Postal code
1989934148
Approval date
2017-11-26, 1396/09/05
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.662

Health conditions studied

1

Description of health condition studied
Fatty liver grade 2 and 3 with increased liver enzymes
ICD-10 code
K77
ICD-10 code description
Liver disorders in diseases classified elsewhere

Primary outcomes

1

Description
Liver Enzyme Test
Timepoint
Before the intervention, the fourth session of the intervention and one month after the end of the intervention
Method of measurement
Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Low-level laser therapy with a

wavelength of 830 nm, a power of 35 mW, on four points (right upper, right lower, upper left, lower left of liver or four lobes of the liver) with different jules according to the patient at each point (depth of the liver in The primary sonography is measured and from division of energy over the surface formula will be achieved) 3 times per week for 12 sessions.

Category

Treatment - Devices

2

Description

Control group: Sham laser (silent laser) is used for blindness at the same points as desired. All variables, including the duration of radiation and the number of treatment sessions in the control group, will be exactly the same as the case group, and the treatment will be given by the same physician in this group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Dr Maryam Barati

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 9221

Email

laser.cntr@yahoo.com

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

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

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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

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

Dr Maryam Barati

Position

Non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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