

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of Laser Acupuncture in the treatment of Fatty liver

Protocol summary

Study aim

Determining the effectiveness of laser acupuncture in the treatment of grade 2 and 3 fatty liver (fibrotic tissue) with increased liver enzymes (AST and ALT above 40) in people 30 to 70 years old

Design

The clinical trial has a control group, unblinded and randomized.

Settings and conduct

All patients with grade 2 and 3 fatty liver who referred to SHOHADA Tajrish Hospital. Evaluations are done once before assigning patients to treatment groups, at the end of treatment, and the third and sixth months after the INTERVENTION. Laboratory and paraclinical evaluations are also performed blindly to the treatment group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: grade 2 and 3 fatty liver with increased liver enzymes confirmed by fibroscan and age 20 to 70 years old; full consent to participate in the study and complete the treatment and follow-up process. Patients with diabetes, pregnancy or lactation, hyperlipidemia and hypercholesterolemia, taking any medication in the last month, hepatitis, cardiovascular patients, hypertension, hyper and hypothyroid, fibroid and polycystic ovary, hormonal disorders, age under 20 and over 50 years and receiving laser for any other reason are excluded from the study process.

Intervention groups

The treatment procedure is performed with PLP-IR laser with a power of 300 mW and a wavelength of 810 nm with a dose of 6 joules in each point for 3 times a week and for 12 sessions for 1 month. In the case group, based on traditional Chinese medicine, common points in the treatment of fatty liver are intervened as follows: Points in the body: REN12, GB34, LIV 3-8-13-14, SP6-9, BL18-19-20- 21, ST40-ST36, Hearth 5, Hearth 8, Shenmen, and in ear points: Liv, Shenmen, Spleen and Gallbladder.

Main outcome variables

Grade steatosis; fibrosis grade; biochemical profile;

around the hips; Waist; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N45**

Registration date: **2023-12-24, 1402/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-24, 1402/10/03**

Update count: **0**

Registration date

2023-12-24, 1402/10/03

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Laser Acupuncture in the treatment of Fatty liver

Public title

Evaluation of Laser Acupuncture in the treatment of Fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

In the form of a randomized blinded clinical trial, patients with fibrotic fatty liver with increased liver enzymes (AST and ALT above 40) aged 20 to 70 years who refer to Taleghani Hospital for treatment are examined in terms of inclusion criteria. The criteria for entering the study include grade 2 and 3 fatty liver with increased liver enzymes confirmed by fibroscan and age 20 to 70 years, which is full consent to participate in the study and complete the treatment and follow-up process.

Exclusion criteria:

Patients with diabetes, pregnant and lactating, hyperlipidemia and hypercholesterolemia, taking any medication in the last month, hepatitis, cardiovascular patients, hypertension, hyper and hypothyroid, fibroid and polycystic ovary, hormonal disorders, age under 20 and over 50 years and receiving laser for any other reason are excluded from the study process.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients are divided into case and control groups based on the table of random numbers with a ratio of 1:1. The assigned group is placed in dark envelopes one after the other. This envelope will be opened by the treating doctor only after the initial evaluation of each person, and neither the patient nor the clinical evaluator will know about his treatment group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

laser application in medical sciences research center, shohada tajrish hospital

City

tehran

Province

Tehran

Postal code

1989934370

Approval date

2018-08-22, 1397/05/31

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.448

Health conditions studied

1

Description of health condition studied

Fatty liver disease with 2 and 3 grading

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Steatosis grading

Timepoint

Before and 1, 3, 6 months after intervention

Method of measurement

Fibroscan

2

Description

Fibrosis grading

Timepoint

Before and 1, 3, 6 months after intervention

Method of measurement

Fibroscan

3

Description

Biochemical profile

Timepoint

Before and 1, 3, 6 months after intervention

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, only periodical tests and fibroscan are performed according to what was said.

Both groups are advised to follow their diet.

Category

N/A

2

Description

Intervention group: The treatment procedure is performed with PLP-IR laser with a power of 300 mW and a wavelength of 810 nm with a dose of 6 joules in each point for 3 times a week and for 12 sessions for 1 month. In the case group, based on traditional Chinese medicine, common points in the treatment of fatty liver are intervened as follows: Points in the body: REN12, GB34, LIV 3-8-13-14, SP6-9, BL18-19-20- 21, ST40-ST36, Hearth 5, Hearth 8, Shenmen, and in ear points: Liv, Shenmen, Spleen and Gallbladder. The laser handle is placed vertically and directly on the point and its light is irradiated. A brief contact with the skin is made during the irradiation to avoid scattering of the irradiated light. During the light radiation, the patient does not feel any heat. Evaluations are done once before assigning patients to treatment groups, once at the end of treatment, and once in the third and sixth months after the end of treatment. Measurements before and after the treatment are done by a skilled doctor independent of the plan who is unaware of the treatment group. Laboratory and paraclinical evaluations are also performed blindly to the treatment group. The desired statistics in this project are based on several sections: 1. Consultation for fatty liver grading before and after the treatment period (fibroscan) 2. Measuring height and weight of patients and calculating BMI as a score obtained by dividing weight in kilograms by the square of height in meters 3. Calculating and giving the appropriate and almost identical treatment regimen to patients based on BMI and increasing sports activity 4. By performing a fibroscan of the liver, the degree of steatosis and fibrosis of the fatty liver and its grade are determined 5. Laboratory evaluations including CBC, diff and AST, ALT, ALKP, fasting blood sugar, triglyceride, total cholesterol, LDL and HDL, BUN, Cr, TSH, T4, Vit D and insulin will be measured as laboratory criteria before treatment. For the tests, the patient is asked to fast for at least 12 hours. About 10 cc of blood is received from the patient and sent as a clot to the laboratory of Tajrish Martyrs Hospital for laboratory examination. 6. In order to check the quality of life, the Short Form-36 questionnaire is used, which examines the physical and mental health of the person. The SF-36 questionnaire contains 11 questions about physical health and mental health. 7. After the end of the treatment, the above tests are repeated and the

patients are again subjected to fibroscan and blood test. Fibroscan and tests are repeated three months and six months later.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Zahra Razzaghi

Street address

Shohadaye-Tajrish Hospital, Shahr-dari St., Tajrish Sq,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Yaman st, Danshjoo Blvd, Velenjak st

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1985717443

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info@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

Mohammad Reza Razzaghi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Jahani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The publication is in the form of an article and it is not necessary to provide data in the article

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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Somayeh Jahani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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