Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
Fibrscan

2

Description
Fibrosis grading

Timepoint
Before and 1, 3, 6 months after intervention

Method of measurement
Fibrscan

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 fiberscan 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 meters3. 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 determined5. 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

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Shohadaye-Tajrish Hospital, Shahrdari St., Tajrish Sq,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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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