Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of laser acupuncture in the treatment of obesity and associated metabolic disorders

Protocol summary

Study aim
Determining the efficacy of laser acupuncture in the treatment of central obesity Determining the Effectiveness of Acupuncture Laser in Improving Obesity Metabolic Problems

Design
40 patients are divided into case and control groups according to random number table with 1: 1 ratio The assigned group is consecutively inserted into dark envelopes. This envelope is used only after evaluations Initially each individual is returned by a physician and neither the patient nor the clinical evaluator will be informed of their treatment group

Settings and conduct
24 sessions, three sessions per week, for all patients, including case and control, are given at specified intervals for ten seconds

Participants/Inclusion and exclusion criteria
Body mass ≥ 25 and complete consent to participate in the study and complete the follow-up and follow-up are excluded. Epilepsy and Cancer Epilepsy Mental Disorders, Infectious Diseases of the Skin or Light Sensitivity Are Not Included in the Stud

Intervention groups
The subjects in the study were randomly divided into intervention and control groups. The intervention group will be treated with laser acupuncture three times a week for 4 weeks The acupuncture laser is based on a well documented global system and on previously documented locations No needles are used in this method, and only low-power laser light is used to stimulate the spot. In the control group similar points with the same frequency are treated with a silent laser for placebo effect

Main outcome variables
Body mass changes and weight changes and hunger changes as well as body size changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111121008146N31**
Registration date: **2019-10-14, 1398/07/22**
Registration timing: **retrospective**

Last update: **2019-10-14, 1398/07/22**
Update count: **0**

Registration date
2019-10-14, 1398/07/22

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

Email address
laser.cntr@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-20, 1396/10/30

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of laser acupuncture in the treatment of obesity and associated metabolic disorders

Public title
The effect of laser in the treatment of obesity

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Estimation of body mass index ≥ 25 and complete consent to participate in the study and complete the treatment process

Exclusion criteria:
patients with known diseases such as cardiovascular diabetes mellitus If you have epilepsy Tumors cancer mental disorders contagious skin infections light-sensitization not be pregnant or breastfeeding They were excluded if they took any of the drugs that were effective on weight within one month before the study Kidney Disorders Endocrine Disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
All patients are divided into two groups of case and control on the basis of 1: 1 random numbers table.

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
2018-01-06, 1396/10/16

Ethics committee reference number
IR.SBMU.RETECH.REC.1396.862

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E74.09

ICD-10 code description
Other glycogen storage disease

Primary outcomes

1

Description
Body mass

Timepoint
One time before patients were assigned to groups and one time at the end time

Method of measurement
Laboratory testing and ultrasound

Secondary outcomes

1

Description
Body mass and body size changes due to fat loss

Timepoint
One time before patients were assigned to groups and one time at the end time

Method of measurement
Laboratory testing and sonography and sf36 questionnaire

Intervention groups

1

Description
Intervention group: Patients undergo low-power laser. It is non-toxic and non-toxic and has high immunity. Light is shed at very specific points according to acupuncture for ten seconds and three times a week

Category
Treatment - Other

2

Description
Control group: Patients are put on a low-power laser and are given acupuncture points for ten seconds and three times a week
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Mohammad Reza Razaghi
Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran
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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 Razaghi
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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
Mohamadreza razaghi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Others
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Person responsible for updating data

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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
Not applicable