

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison between the effects of Dietary Therapy and exercise, Acupuncture, Laser Acupuncture therapy in weight loss of obese and overweight women

Protocol summary

Study aim

Comparing the effects of diet therapy and exercise, acupuncture and laser acupuncture in weight loss

Design

Patients are divided into 4 groups by chance. The first patient enters one of the four groups by random selection. The second patient enters one of the other three groups by random selection. The third patient enters one of the two remaining groups by random selection, and the fourth patient enters the remaining group. The random selection continues for each patient until each group reaches enough.

Settings and conduct

Eligible people are included in the study after obtaining personal consent. After the anthropometric evaluation, the patients are randomly divided into 4 groups: a group of diet therapy and exercise, an acupuncture group with diet therapy and exercise, a laser therapy group with diet therapy and exercise, and a combination group of laser and acupuncture with diet therapy and exercise. Evaluations will be done at baseline and three months later with 12 sessions of interventions. Laboratory information including blood sugar and blood pressure will also be measured. Acupuncture and laser points will be performed based on existing standard protocols by two therapists trained in this field.

Participants/Inclusion and exclusion criteria

without history of mood disorders, anxiety and psychotic disorders, and other psychiatric disorders, and not used psychotropic, hormonal, or steroid drugs in the last 6 months, and he has no history of electroshock therapy.

Intervention groups

Diet therapy and exercise group Acupuncture group with diet therapy and exercise Laser acupuncture group with diet therapy and exercise The combination group of acupuncture and laser acupuncture along with diet therapy and exercise

Main outcome variables

weight, fat mass and fat-free mass

General information

Reason for update

Acronym

طب سوزنی لیزری

IRCT registration information

IRCT registration number: **IRCT20111121008146N42**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

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

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between the effects of Dietary Therapy and exercise, Acupuncture, Laser Acupuncture therapy in weight loss of obese and overweight women

Public title
Comparison between the effects of Dietary Therapy and exercise, Acupuncture, Laser Acupuncture therapy in weight loss of obese and overweight women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women 18 to 50 years old Has a bmi between 25 and 39.9
Exclusion criteria:
 Dissatisfaction at any time A history of suffering from mood disorders, anxiety and psychotic disorders and other psychiatric disorders in the last 6 months using of psychotropic and hormonal drugs and steroid drugs in the last 6 months

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 4 groups by chance. The first patient enters one of the four groups by random selection. The second patient enters one of the other three groups by random selection. The third patient enters one of the two remaining groups by random selection, and the fourth patient enters the remaining group . The random selection continues for each patient until each group reaches enough.

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

کمیته سازمانی اخلاق در پژوهشهای زیست پزشکی

Street address

Tehran - Shahid Chamran Highway, Yemen Street - Shahid Arabi Street, next to Ayatollah Taleghani Hospital

City

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Province

Tehran

Postal code

1985717443

Approval date

2022-11-13, 1401/08/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.544

Health conditions studied

1

Description of health condition studied

Overweight and obese women

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Overweight

Timepoint

Three months later

Method of measurement

measuring weight with a Seka scale

Secondary outcomes

1

Description

Abdominal fat

Timepoint

Three months later

Method of measurement

determining fat mass with a Body Composition Analyzer

Intervention groups

1

Description

control group: diet therapy and exercise group

Category

Treatment - Devices

2**Description**

Intervention group 1: In addition to diet and exercise, acupuncture treatment should also be done.

Category

Treatment - Other

3**Description**

Intervention group 2: In addition to diet and exercise, laser acupuncture is performed.

Category

Treatment - Other

4**Description**

Intervention group 3: In addition to diet and exercise, acupuncture treatment and laser acupuncture are also performed respectively.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina medical center

Full name of responsible person

Arista Shojaedin

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, Vice-Chancellor of Research Affairs

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Tajrish Square, Tajrish Martyrs Hospital

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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**

Laser Application Research Center in Medical Sciences

Full name of responsible person

Arista Shojaeddin

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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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

Undecided - It is not yet known if there will be a plan to make this available