Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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

Tehran

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 excercise 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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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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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
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Other areas of specialty/work
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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