Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effects of acupuncture and embedding on anthropometric indices and inflammation biomarkers in overweight patients: a randomized placebo-controlled trial

Protocol summary

Study aim
Determining the effectiveness of acupuncture and embedding on anthropometric indices and inflammatory factors in overweight patients in comparison with placebo

Design
Randomized, controlled, phase 3, parallel groups, single blinded clinical trial on 150 overweight patients. Participants will be divided into 3 groups using block randomization method with random allocation software (SPSS). Groups 1 receives acupuncture, group 2 receives embedding and group 3 receives placebo. Participants in group 1 and 3 receive acupuncture and its placebo twice a week for 4 weeks, then once a week for next 4 weeks and for embedding 3 times: at the beginning of study, at week 3rd and 6th.

Settings and conduct
This trial will be held in Ahmadie clinic, Tehran Univerity of Medical Sciences affiliated. After informing the public, volunteers who have inclusion criteria will be divided randomly into 3 groups. Anthropometric indices will be measured at weeks 0, 4, and 8 and data will be analyzed using SPSS software.

Participants/Inclusion and exclusion criteria
Overweight patients (BMI 25-29.9) without any underlying disease, aged 25-65 years old

Intervention groups
1- Acupuncture 2- Embedding 3- Placebo

Main outcome variables
Weight; BMI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171007036614N3**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date
2023-06-27, 1402/04/06

Registrant information

Name
Mohammad Sadegh Adel-Mehraban

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3624 3214

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effects of acupuncture and embedding on anthropometric indices and inflammation biomarkers in overweight patients: a randomized placebo-controlled

trial

Public title
effects of acupuncture and embedding in overweight patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 25-65 years old Overweight patients (BMI 25-29.9)
Exclusion criteria:
Pregnancy Lactation Any significant underlying disease (pulmonary, cardiovascular, liver, cancer, etc.) Diet within the past 6 months
Age
From **25 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly divided into 3 groups by the block randomization method (ABA, ACB, BAC, BCA, CAB, CBA). group A receives acupuncture, group B embedding, and group C placebo of acupuncture. A number from 1 to 6 will be assigned to each block. To achieve sample size, 50 numbers (blocks) will be generated by an online random number generator and participants will be assigned to the groups randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be randomly divided into 3 groups. Acupuncture and its placebo is similar and patients can not identify them but embedding is different. So totally blindness for patients and physician is not possible. Outcomes will be measured by a third party who is not aware about group of participants and type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee/institute of Pharmaceuticals Sciences -Tehran University of Medical Sciences
Street address
Enqelab St.
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Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-03-14, 1401/12/23
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.140

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Weight
Timepoint
Before treatment, after 4 weeks, and after 8 weeks
Method of measurement
Digital scale

2

Description
Body mass index
Timepoint
Before treatment, after 4 weeks, and after 8 weeks
Method of measurement
Divide weight by height squared

Secondary outcomes

1

Description
IL-6
Timepoint
Before treatment and after 8 weeks
Method of measurement
ELISA

2

Description
IL-10

Timepoint
Before treatment and after 8 weeks
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Acupuncture. To perform acupuncture, stimulation of st40, st36, st44, lv2, lv3, st25, st26, st27, ren4, ren6, ren10, ren12, sp13-15, gb26, st32, Li13 acupoints will be performed. Acupuncture with disposable steel needles of quanqi brand size 25 x 40 are selected in acupoints based on the predominant obesity syndrome, which is sp qi def and damp. The needles are inserted vertically. In the abdominal, thigh and arm, depending on the patient's body, it is inserted between 1 to 2.5 cm, and in other areas, such as between the fingers and toes, 5 to 7 mm. Due to the predominant syndrome of patients in places such as st40, st36, st25, sp15, the tonification technique is used and in other points even technique are used. The needles stay in place for about 20 minutes. Some points such as st25, ren12, ren4, 26 gb are connected to the electrode and after 20 minutes the device is turned off, the connection is disconnected and the needles are removed. The frequency of the device will be between 10-15 Hz, depending on the patient's tolerance. The electrode will be from KWD brand and the same for patients. Each participant will receive acupuncture protocol twice a week for 4 weeks and then once a week until the end of the eighth week.
Category
Treatment - Other

2

Description
Intervention group: Embedding. Stimulation of St24-26, Ren4, Ren6, Ren10, Ren12, Kd17 in sterile condition using absorbable sutures each 3 weeks for 3 sessions (weeks 0, 3 and 6 of study) will be performed.
Category
Treatment - Other

3

Description
Control group: Acupuncture placebo. For acupuncture placebo, disposable 18 x 20 needles of quanqi brand are used. Points that are not acupoints and are at least 1 cm away from the acupoints will be selected carefully. The needle penetrates the skin up to 2 mm and even less in the hand area (only a small contact) and tries not to have a manipulation process and the needle is not deeper. To electro simulate, needles are attached to the device, the device is turned on but the patient does not receive a frequency. For this group, the needles stay in the body for 20 minutes and then come out. Each participant will visit twice a week for up to 4 weeks and then once a week until the end of the eighth week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadie clinid
Full name of responsible person
Mohammad Sadegh Adel Mehraban
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Sadegh Adel Mehraban

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Name of organization / entity

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Position

PhD student

Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Gathered data will be analyzed and then published.

When the data will become available and for how long

After publishing study

To whom data/document is available

Everyone (depending on the journal policies)

Under which criteria data/document could be used

Published article will be public.

From where data/document is obtainable

The journal that the paper is published in.

What processes are involved for a request to access data/document

Just sending Email to corresponding author.

Comments