

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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). Group 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 University 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)

###### Phone

+98 31 3624 3214

###### Email address

sadeghadel@gmail.com

##### 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.

### City

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 clinic

**Full name of responsible person**

Mohammad Sadegh Adel Mehraban

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Taleqani St.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**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?**

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  
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Traditional Medicine  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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