

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### effectiveness of acupuncture on blood sugar and insulin in women with pre-diabetes

#### Protocol summary

##### Study aim

The effect of reduce appetite acupuncture on fasting blood sugar and insulin in pre-diabetic patients compared to the control group

##### Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 102 patients. A random block method was used for randomization

##### Settings and conduct

102 female patients aged 20-60 referred to the diabetes control clinics of Mazandaran University of Medical Sciences, who were diagnosed with pre-diabetes according to the criteria of ADA2023 by the doctor, after filling out the consent form. The participants in the research project are trained in lifestyle and nutrition counseling and their demographic information and fasting blood sugar tests and insulin levels are recorded. location: sports medicine clinic

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Women aged 20-60 with pre-diabetes. Have consent to participate in the study. BMI $\geq$ 25. Suffer from convulsions, allergies to metals, blood coagulation diseases, various cancers, infectious and skin diseases, and do not have a heart pacemaker. Not pregnant or lactating. Do not undergo drug, hormonal and herbal treatment for blood sugar control. There is no other endocrine disorder disrupting blood sugar control according to the diagnosis of an endocrinologist (including Cushing's disease, etc.). Do not use corticosteroids. Exit criteria: Announcing withdrawal from continuing to participate in the plan. Absence of acupuncture sessions for more than two sessions. Emergence of acupuncture contraindications during the

##### Intervention groups

Compliance with lifestyle and nutrition recommendations for 8 weeks+ acupuncture at 10 acupuncture points - 2 sessions per week - with an interval of 48 hours - by acupuncture needles with a size of 0.25 x 25 - for 20 minutes in each session

#### Main outcome variables

Fasting blood sugar and insulin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230723058893N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

##### Registration date

2023-12-14, 1402/09/23

##### Registrant information

##### Name

Sahar Bagheri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 6552

##### Email address

dr\_sbagheri@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-02, 1402/05/11

##### Expected recruitment end date

2024-06-22, 1403/04/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

effectiveness of acupuncture on blood sugar and insulin in women with pre-diabetes

**Public title**

effectiveness of acupuncture on blood sugar and insulin in women with pre-diabetes

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Women aged 20-60 with pre-diabetes Diagnosis according to ADA2023 criteria and given by the attending physician and have received the necessary lifestyle and nutritional recommendations 3. Have consent to participate in the study 4. BMI $\geq$ 25 5. Not suffering from convulsions, allergies to metals, blood coagulation diseases, various cancers, infectious and skin diseases, and not having a heart pacemaker 6. Not pregnant or lactating 7. Do not undergo drug, hormonal and herbal treatment for blood sugar control 8. There is no other endocrine disorder disrupting blood sugar control according to the diagnosis of an endocrinologist (including Cushing's disease, etc.) 9. Do not use corticosteroids

**Exclusion criteria:****Age**

From **20 years** old to **60 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **102**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random block method is used to control the unknown intervening variables. In addition to controlling the intervening variables, if the study is not continued due to unknown problems, the groups included in the study are almost equal, to do this, blocks of 4 will be used and randomly. Randomization will also be done by Random allocate software as follows. This randomization is based on the order of patients entering the clinic.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this plan, the statisticians are only blind, and according to the coding of the patients, they are not aware of the name of the patient group, and the group is determined according to the protocol of random codes in the table

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Committee of Imam Khomeini Hospital in Sari

**Street address**

Amir Mazandarani Boulevard, Imam Khomeini Hospital

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Approval date**

2023-03-13, 1401/12/22

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1402.17282

**Health conditions studied****1****Description of health condition studied**

prediabete

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

fasting blood sugar & insulin

**Timepoint**

week 0 and 8

**Method of measurement**

serum level

**Secondary outcomes****1****Description**

Anthropometric measures

**Timepoint**

week 0 and 8

**Method of measurement**

Body analyzer

## Intervention groups

### 1

#### Description

Intervention group: Compliance with lifestyle and nutrition recommendations for 8 weeks, in addition, acupuncture at 10 acupuncture points - 2 sessions per week - with an interval of 48 hours (16 sessions in total) - by acupuncture needles with a size of 0.25 x 25 with a depth of 1 centimeters in non-ear areas and gently - for 20 minutes in each session and under sterile conditions with alcohol cotton - by a trained assistant in points Stomach point-(Ren 6) Guanyuan- Liangmen (St 21)- Tianshu (St 25)- Zusanli (St 36)- CV-12 (Zhongwan

#### Category

Treatment - Devices

### 2

#### Description

Control group: Compliance with lifestyle and nutrition recommendations for 8 weeks

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sports medicine clinic

##### Full name of responsible person

Sahar Bagheri

##### Street address

Razi 3

##### City

Sari

##### Province

Mazandaran

##### Postal code

4816868890

##### Phone

+98 11 3336 6552

##### Email

dr\_sbagheri@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Pedram Ebrahimnejad

##### Street address

Moalem Square

##### City

sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۷۳۳۹۷۱

##### Phone

+98 11 3325 7230

##### Email

pajhooeshi@mazums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Sahar Bagheri

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Sport Medicine

##### Street address

razi 3

##### City

sari

##### Province

Mazandaran

##### Postal code

486868890

##### Phone

+98 11 3336 6552

##### Email

dr\_sbagheri@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Sahar Bagheri

##### Position

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The final Excel file

**When the data will become available and for how long**

2025

**To whom data/document is available**

Medical researchers

**Under which criteria data/document could be used**

By observing ethics in research

**From where data/document is obtainable**

direct email

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

Direct email to the responsible researcher

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sahar Bagheri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Razi 3 - Mostafavian clinic- sport medicine clinic

**City**

Sari

**Province**

Mazandaran

**Postal code**