

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 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**

prediabet

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
Razi 3 - Mostafavian clinic- sport medicine clinic
City
Sari
Province
Mazandaran
Postal code
4816868890
Phone
+98 11 3336 6552
Fax
Email
dr_sbageri@yahoo.com

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

4816868890
Phone
+98 11 3336 6552
Fax
Email
dr_sbageri@yahoo.com

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