Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating Therapeutic Effects of Acupuncture on Blood Glucose Level among Patients with Type 2 Diabetes Mellitus

Protocol summary

Study aim

The aim of this study is to compare the therapeutic effects of acupuncture with sham acupuncture on fasting blood glucose level and hemoglobin A1c among patients with type 2 diabetes mellitus under treatment with metformin.

Design

Parallel, double blind, sham-controlled randomized clinical trial

Settings and conduct

The study will be conducted on 80 patients with diagnosis of type 2 diabetes mellitus referred to Traditional Medicine clinic affiliated to School of Traditional Persian Medicine, Tehran University of Medical Sciences, that will be randomized to acupuncture (n=40) and sham acupuncture (n=40) groups.

Participants/Inclusion and exclusion criteria

Eligible participants are patients aged between 35 and 65 years with diagnosis of type 2 diabetes mellitus, who are under treatment with metformin to control their blood glucose (500-1500 mg/day), with fasting plasma glucose < 250 mg/dl or HbA1c < 9

Intervention groups

In addition to metformin therapy, patients in the acupuncture group will receive needling at 15 acupoints for 20 min. Control group will be treated with very small needles inserted very shallow (3-5 mm) without a Deqi sensation at the non-acupoints. Both groups will be treated for 12 sessions in 6 weeks (three times per week for two weeks, then two times per week for two weeks, and then once weekly for two weeks), and maintenance treatment will be performed for two sessions once every other week (Totally, 14 sessions of treatment during 10 weeks).

Main outcome variables

Fasting plasma glucose (FPG) will be measured before treatment, and after one, two, four, six and twelve weeks of treatment. HbA1c will be assessed once before treatment and once twelve weeks after the initiation of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180914041035N1**
Registration date: **2018-10-11, 1397/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-11, 1397/07/19**
Update count: **0**

Registration date

2018-10-11, 1397/07/19

Registrant information

Name

Amir Hooman Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-29, 1397/06/07

Expected recruitment end date

2019-02-26, 1397/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating Therapeutic Effects of Acupuncture on Blood Glucose Level among Patients with Type 2 Diabetes Mellitus

Public title
Effect of Acupuncture in Treatment of Diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diagnosis of type 2 diabetes mellitus according to American diabetes association diagnostic criteria, who are under treatment with metformin to control their blood glucose (500-1500 mg/day) Signed the written informed consent Fasting plasma glucose between 140-250 mg/dL Aged 35-65 years

Exclusion criteria:
Cardiovascular diseases (history of heart failure, New York heart association function class III-IV, myocardial infarction, acute coronary syndromes, pacemaker implantation, coronary revascularization and stroke) Renal impairment (urinary albumin excretion ≥ 30 mg/day, estimated glomerular filtration rate < 60 mL/min/1.73 m2) Hepatic impairment (abnormal serum aminotransferases, liver cirrhosis) Cognitive impairment, inability of cooperation Fasting plasma glucose ≥ 250 mg/dL or hemoglobin A1C ≥ 9 Pregnancy or breastfeeding Diabetic patients that use other medications than metformin to control their blood glucose such as insulin Evidence of lower limb infection, wound and ischemia (ecchymosis, bright skin, ABI<0.9)

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned following simple randomization procedures to either acupuncture group (treatment group) or sham acupuncture group (control group) by means of a random number table prepared by an independent member. The allocation sequence will be concealed from the researchers in sequentially numbered, sealed, opaque envelopes. After the researcher has assessed eligibility, obtained the patient's consent, and completed all baseline assessments of the enrolled participants, corresponding envelopes will be opened, and the treatment allocation will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
All participants will be blinded to the treatment assignments. The primary investigator will be blinded to patients' information and the results from the measurements, however blinding the primary researcher from participants' allocation is not possible. The data will be analysed by an independent outcome assessor who will be kept blinded to the participants' allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
6th floor, central building, Qods street, Keshavarz Blvd

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Approval date
2018-08-28, 1397/06/06

Ethics committee reference number
IR.TUMS.VCR.REC.1397.369

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes Mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting plasma glucose

Timepoint
Evaluating Fasting plasma glucose at baseline (before the treatment), and 1, 2, 4, 6 and 12 weeks after the

initiation of treatment

Method of measurement

Laboratory kit

Secondary outcomes

1

Description

Hemoglobin A1c

Timepoint

Evaluating HbA1c at baseline (before the treatment) and 12 weeks after the initiation of treatment

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: Acupuncture. According to textbooks, literature review and the clinical experience of the principal researcher, fifteen body acupoints were selected including Waiguan (TE 5), Tianshu (ST 25), Zusanli (ST 36), Fenglong (ST 40), Qihai (CV 6), Zhongwan (CV 12), Feishu (BL 13), Pishu (BL 20), Shenshu (BL 23), Xuehai (SP 10), Sanyinjiao (SP 6), Taichong (LR 3), Hegu (LI 4), Quchi (LI 11) and Taixi (KI 3). Sterile stainless steel acupuncture needles (0.25mm × 40mm, Zhongyan Taihe medical instrument, Beijing, China) will be inserted perpendicularly at a depth of 10-15 mm into the acupoints, and after the needle sensation (Deqi) is arrived, they are retained for 20 minutes. The treatment will be performed for 12 sessions in 6 weeks (three times per week for two weeks, then two times per week for two weeks, and then once weekly for two weeks), and maintenance treatment will be performed for two sessions once every other week (Totally, 14 sessions of treatment during 10 weeks).

Category

Treatment - Devices

2

Description

Control group: Sham acupuncture. Very small needles (0.16mm × 7mm) will be inserted very shallow (3-5mm) without a Deqi sensation at the non-acupoints matched to the actual acupunctre points and they are retained for 20 minutes. The treatment will be performed for 12 sessions in 6 weeks (three times per week for two weeks, then two times per week for two weeks, and then once weekly for two weeks), and maintenance treatment will be performed for two sessions once every other week (Totally, 14 sessions of treatment during 10 weeks).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine Clinic of Traditional Persian medicine School of Tehran University of Medical S

Full name of responsible person

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Sponsors / Funding sources

1

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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
Amir Hooman Kazemi

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Traditional Medicine

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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