# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

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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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Tehran

**Province**
Tehran

**Postal code**
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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

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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**

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## Person responsible for updating data

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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