

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the effect of warm salt water foot bath on control of blood glucose in type2 Diabetic patients with cold temperament

Protocol summary

Study aim

Determining the effect of warm salt water bath on blood Glucose control in type 2 diabetic patients with cold temperament

Design

Clinical trial with control group, parallel groups, randomized by epidemiologist (randomized balanced block method), on 52 patients.

Settings and conduct

Diabetic patients referring to Salamatkade Iranian Medicine in Qom and Endocrine Clinic of Qom Kamkar Hospital who have the study inclusion criteria are selected by the researcher, then the details of the study will be explained by the researcher, then a questionnaire of demographic characteristics and disease information will be prepared and Patients are randomly assigned to one of two treatment groups.

Participants/Inclusion and exclusion criteria

inclusion Criteria: 1. Diabetic patients with a cold temperament and aged 20 to 60 years 2. FBS>130 or HGA1C between 7 and 10 3. Not starting to take antidiabetic drugs (herbal and non-herbal) from one month before entering the study 4. Consent to not using treatments outside the protocol Non inclusion Criteria: 1. Unstable kidney, heart and brain complications and history of other diseases (types of malignancies, rheumatological diseases, thyroid diseases and other hormonal diseases, other special diseases) 2. Patients who have received systemic corticosteroids in the last month ulcerous lesions on the foot Pregnancy and breastfeeding 3. Using alternative medical therapy such as massage, cupping, etc. during the month before the study 4. Patients who have a history of blood pressure less than 100 mmHg or who have had orthostatic hypotension 5. proteinuria, hematuria 6. hypermenorrhea 7. DVT, severe foot edema

Intervention groups

Intervention group: using warm salt water foot bath(Abzan) Control group: Without using foot bath

Main outcome variables

blood glucose control(FBS,HGA1C,Serum Insolin)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058314N1**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

zahra sadat salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3776 4073

Email address

zsalehi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of warm salt water foot bath on control of blood glucose in type2 Diabetic patients with cold temperament

Public title

"foot bath in control of Diabetes"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic patients with a cold temperament and aged 20 to 60 years FBS>130 or HGA1C between 7 and 10 Not starting to take antidiabetic drugs (herbal and non-herbal) from one month before entering the study Consent to not using treatments outside the protocol

Exclusion criteria:

Unstable kidney, heart and brain complications and history of other diseases (types of malignancies, rheumatological diseases, thyroid diseases and other hormonal diseases, other special diseases) Patients who have received systemic corticosteroids in the last month ulcerous lesions on the foot Pregnancy and breastfeeding Using alternative medical therapy such as massage, cupping, etc. during the month before the study Patients who have a history of blood pressure less than 100 mmHg or who have had orthostatic hypotension proteinuria, hematuria hypermenorrhea DVT, severe foot edema

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>). Allocation concealment is also guaranteed due to the use of special codes generated by the website.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Working Group/Committee of Ethics in Research, Qom University of Medical Sciences

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No. 83, Shahid Lotfi Niaser, Shahid Lotfi Niaser, Safashehr St., No. 83

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Province

Markazi

Postal code

3716993456

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.MUQ.REC.1402.029

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

control of blood glucose in type2 Diabetic patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

HGA1C

Timepoint

The beginning of the study and 3 months later

Method of measurement

plasma Glycosylated hemoglobin /lab kit

2**Description**

FBS

Timepoint

The beginning of the study and 3 months later

Method of measurement

lab kit

3**Description**

Serum Insolin

Timepoint

The beginning of the study and 3 months later

Method of measurement

lab kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for 3 months, every other night, (before going to bed), sitting on a chair with a support and legs in an angled position and extended up to the top of the wrist in the same special container, containing 5 liters of tolerable and pleasant warm water (between 41 to 37 degrees Celsius) to which 250 grams of salt is added and dissolved in it; They put for 30 minutes. During the work, the temperature of the water in the container must remain the same (for this purpose, the water heater of Tan Aram Hiran, a member of the Qom Medical Sciences Development Center is used) and the surrounding air must be balanced so that the participant does not feel cold. Only about 5 cm above the wrist will be uncovered so that the patient's body does not get cold. It is also explained to the participants to use city tap water to prepare hot water. At the end of the work, after drying the feet with a towel, wear socks and rest. The salt used in this study was prepared and refined from the Jahrom salt mine and has a special brand of Mosallas Salamat Company. The amount of salt required for each session has been prepared by the presenter in 250 gram packages to ensure the same plan between the participants.

Category

Treatment - Devices

2

Description

Control group: There is no intervention (warm water and salt are not prescribed)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamkar hospital

Full name of responsible person

zahra sadat salehi

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19th Street, Charrah Bazar, Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Rahim Aali

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No.83 ,Lotfi Niasar., Jahad Daneshgahi , Safa Shahr St.

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Zahra sadat Salehi

Position

Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Data will be sent by researchers upon request.

When the data will become available and for how long

All potential data can be shared after de-identifying individuals.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be used only for use in published research articles and will not be made available to the public in any other way.

From where data/document is obtainable

To receive the desired documents and data, please refer to the Faculty of Traditional Medicine of Qom University of Medical Sciences.

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

The data will be accessible from the time of announcing the request to the responsible person and proving the scientific documents of the applicant that they are working researchers at the university, as well as reviewing the relevant study and research.

Comments