Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of davayebalgham capsule (a Persian medicine product) and acupuncture on blood sugar and lipid profile of type 2 diabetic patients (a randomized clinical study)

Protocol summary

Study aim
The effect of davayebalgham capsule and acupuncture on blood sugar and lipid profile of type ۲ diabetic patients

Design
A clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on 105 patients. randomization with blocks of three is used by statistical software (SPSS).

Settings and conduct
Sampling will be done among the patients referred to the clinics affiliated with Tabriz University of Medical Sciences. After referring the candidates, a complete history is taken from them and the entry and exit criteria are evaluated. If they agree to participate in the project, the candidates will be randomly divided into three groups. Group one: herbal medicine, group two: placebo, and group three: will undergo acupuncture. Then the studied variables are recorded at the beginning of entering the design. At the beginning and end of 12 weeks, biochemical parameters are measured and recorded through a blood test after at least 12 hours of fasting by taking 8 cc of blood and other variables. In order to perform acupuncture, stimulation of st40, sp6, Li11, sj5, st25, Lu7, du20, ren4, ren17, and ren12 points will be made for 20 minutes with a size of 25 x 40. (once a week for 12 weeks)

Participants/Inclusion and exclusion criteria
Patients with type 2 diabetes without specific underlying disease in the age range of 20 to 65 years

Intervention groups
1- davayebalgham product receiving group 2- Placebo, davayebalgham product receiving group 3- Acupuncture receiving group

Main outcome variables
Fasting blood sugar؛ Cholesterol؛ Triglycerides

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220502054721N1**
Registration date: **2022-10-22, 1401/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-22, 1401/07/30**
Update count: **0**

Registration date
2022-10-22, 1401/07/30

Registrant information

Name
maryam rahimzade

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8897 4535

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of davayebalgham capsule (a Persian medicine product) and acupuncture on blood sugar and lipid profile of type 2 diabetic patients (a randomized clinical study)

Public title
The effect of davayebalgham capsule and acupuncture on type 2 diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Type 2 Diabetes patients Taking oral hypoglycemic drugs Age 20-65 years Satisfaction to enter the plan HbA١C < %٩

Exclusion criteria:
Having serious gastrointestinal diseases including active stomach ulcers and gastrointestinal bleeding History of diabetic ketoacidosis, non-ketone hyperosmolar diabetic coma, severe infection or surgery in the previous month Kidney failure, liver dysfunction, cancers, cysts or breast mass, metabolic diseases Having a psychological illness Consumption of alcohol, drugs or psychotropic substances Uncontrolled hypertension (blood pressure greater than or equal to 100/160 mm Hg) History of myocardial infarction Taking anticoagulants (warfarin and Plavix ...) Insulin therapy over the past three months Continued use of herbs or other herbal medicines Fasting blood sugar above 180 Pregnancy, breastfeeding Having allergies to any of the plants

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are divided into three groups in a random triple block (by SPSS software). They receive a group of herbal medicine, a group placebo of herbal medicine, and a group of acupuncture. After consenting to participate in the plan, people are randomly placed in one of the mentioned groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are unaware that they are in the herbal intervention or placebo group.

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
No. 27، North Sarparsat Street، at the beginning of West Taleghani Street، Palestine Square

City
Tehran

Province
Tehran

Postal code
1416663361

Approval date
2022-02-21, 1400/12/02

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1379

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood sugar

Timepoint
The beginning of the study, 3 months later

Method of measurement
laboratory kit

2

Description
Blood cholesterol

Timepoint
The beginning of the study, 3 months later

Method of measurement
Laboratory kit (blood test)

3

Description
Blood triglycerides

Timepoint

The beginning of the study, 3 months later

Method of measurement

Laboratory kit (blood test)

Secondary outcomes

1

Description

HbA1C

Timepoint

The beginning of the study, 3 months later

Method of measurement

Laboratory kit (blood test)

Intervention groups

1

Description

Intervention group: Davaebalgham product. After the raw materials of this formulation including mastic gum, Trachyspermum ammi (L.) Sprague, Nigella sativa L and Zataria multiflora Boiss were obtained from the market of medicinal plants, a sample of plants was identified and A herbarium code is assigned to each sample. The quality control of the raw materials was done and the plants were ground and mixed with equal proportions of the powders of four plants. The mixed powder of four plants is formulated in the form of 500 mg hard gelatin capsules, so that each patient will receive 2.5 grams of the mixed plant powder in the form of medicinal capsules. For this purpose, each participant will receive the desired dose in 6 capsules of 500 mg (2 after breakfast, 2 after lunch and 2 after dinner) for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Davaebalgham placebo.Placebo capsules will be filled with avicel and toast powder, and in order to match the color and smell of the content inside the capsules, edible colors and a very small percentage of essential oil will be used. Standardization of the product will be done by determining the amount of thymol by gas chromatography-mass spectrometry and determining the amount of total phenol.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Asadabadi Hospital

Full name of responsible person

Maryam Rahimzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Maryam Rahimzade

Position

Assistant

Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The collected data are published in the form of an article after analysis.
When the data will become available and for how long
After publishing the results
To whom data/document is available
Everyone (depending on magazine policies)
Under which criteria data/document could be used
The published study will be public
From where data/document is obtainable
The journal in which the article was published Author's Email: maryam rahimzade m-rahimzade@razi.tums.ac.ir
What processes are involved for a request to access data/document
After sending the email to the responsible author, the email will be answered within one month at most.
Comments