

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Efficacy of a traditional anti-diabetic herbal composition on glycemic, inflammatory, and oxidative stress parameters in patients with type 2 diabetes. A double-blind randomized clinical trial study

Protocol summary

Study aim

Efficacy of a traditional anti-diabetic herbal composition on glycemic, inflammatory, and oxidative stress parameters in patients with type 2 diabetes

Design

This study is a double-blind and parallel clinical trial that will be conducted in two groups of 35 people on patients with type 2 diabetes referred to Endocrinologists.

Settings and conduct

Patients with type 2 diabetes referred to endocrinologists in Kerman city will randomly receive herbal syrup or placebo in two groups of 35 people in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 65 years, consistent diet and exercise program, having HbA1c more than 6.5 and taking standard medicine except insulin. Exclusion criteria: CABG surgery, the occurrence of ASC, heart attack and stroke, use of anti-inflammatory drugs such as aspirin, the presence of cancer, pregnancy, smoking and alcohol consumption.

Intervention groups

The intervention group will drink herbal syrup and the control group will drink placebo.

Main outcome variables

HOMA-estimated insulin resistance

General information

Reason for update

Acronym

NOSHIN diabetes

IRCT registration information

IRCT registration number: **IRCT20221216056833N2**

Registration date: **2023-12-29, 1402/10/08**

Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**

Update count: **0**

Registration date

2023-12-29, 1402/10/08

Registrant information

Name

Hossein Pourghadamyari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3132 5829

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2024-11-17, 1403/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a traditional anti-diabetic herbal composition on glycemic, inflammatory, and oxidative stress parameters in patients with type 2 diabetes. A double-blind randomized clinical trial study

Public title

The effect of Noshin Shahd herbal syrup on the glycemic index of patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 65 years
Consistency of diet and exercise program
Body mass index less than 35
HbA1c more than 6.5
Not receiving insulin
The patient should take standard medicine except insulin

Exclusion criteria:

Performing CABG surgery, occurrence of ASC, heart and brain stroke, pulmonary embolism, deep vein thrombosis or TIA in the last 1 year
Taking anti-inflammatory drugs such as aspirin with an anti-inflammatory dose, antioxidant supplements, vitamins and omega-3 capsules (<1 g/day), and immunosuppressive drugs in the last three months
Presence of cancer, liver and thyroid diseases
pregnancy
Smoking and alcohol consumption

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will be according to the stratified randomization method. Stratification of patients will be performed based on age, gender, and BMI, With the help of Winpepi software (V 11.6).

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug or placebo in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the medicine, evaluator, and patient will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

It reminds us that the extract of ten plants effective in the treatment of type 2 diabetes, produced by Noshin Shahd Urmia company, is mass produced with health license number 12.14484 since 2018. This product contains the effective ingredients of common safe medicinal plants that are effective in the treatment of type 2 diabetes. It should be noted that during the 4 years of providing the product to the applicants, while declaring the satisfaction of the customers with the performance of the product, no toxicity or complaints

have been reported from the people consuming the extract of ten plants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Postal code

7616913555

Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.KMU.REC.1402.291

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11.7

ICD-10 code description

Type 2 diabetes mellitus with multiple complications

Primary outcomes

1

Description

HOMA-estimated insulin resistance

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

fasting insulin (mU/mL) × fasting glucose (mg/dL)/405

Secondary outcomes

1

Description

Oxidative stress factors

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

Spectrophotometry, Elisa kit

2

Description

Inflammatory biomarkers

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

Elisa kit, Turbidimetric assay

3

Description

Glycemic status

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

Biochemistry Autoanalyzer, Column chromatography, Elisa kit

4

Description

Hematopoietic status

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

CBC

5

Description

Biochemistry factors and lipid profile

Timepoint

Before the intervention and 40 days after the intervention

Method of measurement

Enzymatic assay

Intervention groups

1

Description

Intervention group: All the volunteers who meet the entry criteria were directed to the laboratory so that biochemical tests can be performed on them before taking the drug. Volunteers are asked to take the received medicine three times a day after food. It is worth mentioning that the patients will be divided into two groups by a person outside the research team, one group will drink herbal syrup and the other group will receive a placebo. A placebo with the same appearance as herbal syrup will drink nectar. On a weekly basis, the researcher will make phone calls with the applicants and, while reminding and recording the amount of herbal syrup consumed by drinking nectar, will also ask about the possible side effects of consuming herbal syrup

drinking nectar. Then, at the end of the six week, the patient was asked to visit the clinic for a final evaluation. In this stage, the patient is asked about possible side effects, and the last stage of sample collection will be done to review all the tests of the next stage of receiving the drug (biochemical tests). Return at the end of week 6.

Category

Treatment - Drugs

2

Description

Intervention group: It is worth mentioning that the placebo with the same appearance as the herbal syrup will be drinking nectar. On a weekly basis, the researcher can contact the applicants by phone and while reminding them to use the placebo, they will also be informed about the possible side effects of its use. Biochemical tests will be performed on them before taking the placebo. The volunteers were asked to take the received placebo three times a day after meals. Then, at the end of the sixth week, the patient was asked to visit the clinic for a final evaluation. At this stage, the patient will be asked about possible side effects, and the last stage of sample collection will be done to review all the tests for the next stage of receiving the placebo (biochemical tests).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipur Endocrine Research Center

Full name of responsible person

Mohammad hossein Gozashti

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2

Recruitment center

Name of recruitment center

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

30

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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Kerman University of Medical Sciences
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Faegheh Bahri
Position
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Person responsible for updating data

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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When the data will become available and for how long

Access to study documentation after results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions, and also people who are working in the industry can apply for them.

Under which criteria data/document could be used

For secondary studies

From where data/document is obtainable

The applicant can go to the herbal and traditional medicine research center or submit his request by phone, then after checking by the group members, the documents will be sent to the individual. Address of the Herbal and Traditional Medicines Research Center: Kerman, Haft Bagh Alavi Blvd., Pardizeh University of Medical Sciences Complex, Nursing Faculty, third floor of the Herbal and Traditional Medicines Research Center Phone: 31325318 Fax: 31325318 Email: khtmr.center@kmu.ac.ir The name of the sampler: Ms. Faegheh Bahri Phone: 09361261331 Email: faegheh.bari9797@gmail.com

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

The request sent will be reviewed by the members of the center. If the members agree, they will be notified. The applicant can go to the Herbal and Traditional Medicines Research Center and submit his request to receive the documents, then if the respondents agree with the communication method mentioned in the previous section, the published documents will be available to the patients. Put. In addition, before the start of the work, the number and email of the sampler are given to the patients, and the patients receive information about their tests from the sampler. It should be noted that the sampler in this project is in contact with the patients during the entire follow-up period. In addition, the data and documents related to this plan will be available to patients after the official release of the information, and before the release, only the information related to the patients' tests will be available to them.

Comments

There is no further information.

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

A part of the data such as the information related to the main outcome or the like can be shared.