

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effects of hydroalcoholic herbal extract on glycemic status and lipid profile in patients with type 2 diabetes

Protocol summary

Study aim

- Determination and comparison the effects of hydroalcoholic herbal extract and placebo on blood glucose status (FBS, HbA1c) in patients with type 2 diabetes - Determining and comparison the effects of hydroalcoholic herbal extract and placebo on lipid profile (TC, TG, LDL-C, HDL-C) in patients with type 2 diabetes - Determining and comparing the effects of hydroalcoholic herbal extract and placebo on anthropometric indices (weight, body mass index, waist circumference, hip circumference) in patients with type 2 diabetes

Design

Triple-blinded randomized clinical trial

Settings and conduct

Patients with diabetes who referred to clinics affiliated to Tehran University of Medical Sciences and are treated with hydroalcoholic herbal extract. The extract and container intended for placebo will be exactly the same size and color as the hydroalcoholic herbal extract, and a dark container will be selected for the extract and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic patients Exclusion criteria: Insulin or liraglutide injection - people under 20 and over 70 years - having chronic cardiovascular diseases, major depression, chronic liver and kidney disease, chronic thyroid disorders and malignancies including cancer - taking neuroleptics and Psychotropic, herbal medicines or herbs to control blood sugar over the past 6 months - Patients being treated with a special diet such as vegetarianism or a specific exercise program. People with food or seasonal allergies - Pregnant and lactating women

Intervention groups

Intervention group: Receiving hydroalcoholic herbal extract (3 times a day and 20 drops in a cup of lukewarm water, half an hour before meals) Control group: placebo daily (3 times a day and 20 drops in a cup of lukewarm water, half an hour before meals)

Main outcome variables

Fasting blood glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110314006065N2**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

Registration date

2021-10-13, 1400/07/21

Registrant information

Name

Nazli Namazi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 9630

Email address

nazli.namazi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-09, 1400/07/17

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of hydroalcoholic herbal extract on glycemic status and lipid profile in patients with type 2 diabetes

Public title
Herbal extract & diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes mellitus Age 30 to 70 years
Exclusion criteria:
Insulin or liraglutide injection People under 30 and over 70 Chronic cardiovascular disease, major depression, chronic liver and kidney disease, chronic thyroid disorders and malignancies including cancer Neuroleptics, medical Herbs or herbs to control blood sugar over the past 6 months Patients being treated with a special diet such as vegetarian diets or a specific exercise program. People with food or seasonal allergies Pregnant and lactating women

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible subject be selected with convenience sampling and be randomly assigned into 2 groups of 30 subjects as intervention or placebo with block sizes of 2 with proportion 1:1. A person from research team not involved in the recruitment and assignment of participants will generate allocation sequence using the web site of www.Randomization.com.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants will be randomly assigned to one of two groups: 1) receiving a hydro-alcoholic plant extract, 2) receiving a placebo, and will be examined for 8 weeks. The extract and container intended for placebo will be exactly the same size and color as the plant hydroalcoholic extract, and a dark container will be selected for the extract and placebo. A person from research team not involved in the recruitment and assigning participants generate allocation sequence using web site of www.Randomization.com.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Endocrinology & Metabolism Research Institute
Street address
Endocrinology & Metabolism Research Institute, Shariati Hospital, North Kargar Avenue
City
Tehran
Province
Tehran
Postal code
1411713137
Approval date
2021-07-07, 1400/04/16
Ethics committee reference number
IR.TUMS.EMRI.REC.1400.052

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
fasting blood sugar

Timepoint
Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement
Autoanalyzer

Secondary outcomes

1

Description
Total cholesterol

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Autoanalyzer

2

Description

low-density lipoprotein

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Autoanalyzer

3

Description

High-density lipoprotein

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Autoanalyzer

4

Description

triglyceride

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Autoanalyzer

5

Description

HbA1c

Timepoint

Baseline, after 8 weeks of the intervention (At the end of the intervention)

Method of measurement

Chromatography

Intervention groups

1

Description

Intervention group: Receiving hydroalcoholic herbal extract (3 times a day and 20 drops in a cup of lukewarm water, half an hour before meals) for 8 weeks.

Category

Treatment - Other

2

Description

Control group: placebo which is a mixture of water and permitted dietary color (3 times a day and 20 drops in a cup of lukewarm water, half an hour before meals) for 8 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Institute

Full name of responsible person

Nazli Namazi

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Endocrinology & Metabolism Research Institute, Shariati Hospital, North Kargar Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotuhi

Street address

Vice Chancellor of Research and Technology Tehran University of Medical Sciences, Ghods Street, Keshavarz Square, Tehran, Iran

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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

Nazli Namazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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City

Tehran

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Tehran

Postal code**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