

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effect of diabetes capsule (a TIM product) consumption on lipid profile in patients with hyperlipidemia

Protocol summary

Study aim

This study was designed to investigate the effect of diabetes capsules on improving lipid profile in diabetic patients.

Design

In this study, 70 diabetic patients with impaired lipid profile are divided into two groups of drugs and placebo (35 subjects for each group). The clinical trial phase of this study is 3. Randomization is simple. This study is double-blind. In this study, blood samples are taken before the intervention and after 6 weeks of taking the capsules, and the lipid profile of these people is studied.

Settings and conduct

If the individuals agree to participate in the research, written consent will be obtained from them and their information will be recorded in the relevant questionnaire. The study site is Arak University of Medical Sciences. After 12 hours of fasting blood sampling are taken from the patient. Biochemical tests related to lipid profile are measured. Then, patients with disorders in lipid profile are randomly divided into two groups. One group receives diabetes capsules and the other group receives placebo. This is a double-blind study in which participants and statistical analysts do not know the groups. At the end of the 6-week intervention phase, blood samples are taken again and biochemical factors are measured to evaluate the effectiveness of the diabetes capsule.

Participants/Inclusion and exclusion criteria

Diabetic patients with impaired lipid profile are included in the study. These patients should not have heart disease. If a participant becomes allergic to the capsule during the study or is unable to continue the study, he / she will be excluded from the study.

Intervention groups

The group receiving the drug: This group consume three capsules daily for 6 weeks. The group receiving the placebo: This group consume three capsules daily for 6 weeks.

Main outcome variables

Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141027019705N4**

Registration date: **2020-09-24, 1399/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-24, 1399/07/03**

Update count: **0**

Registration date

2020-09-24, 1399/07/03

Registrant information

Name

Mehdi Salehi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 3331 8165

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m_salehi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of diabetes capsule (a TIM product) consumption on lipid profile in patients with hyperlipidemia

Public title
The effect of diabetes capsules on lipid profile

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Not having known heart disease Having a disorder in lipid profile
Exclusion criteria:
 Unwilling to enter the study Sensitivity to diabetes capsules

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning subjects to each group is that individuals are assigned every other one to one group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The two groups of drug and placebo receive very similar capsules, and they do not know the contents of the capsule The statistical analyzer is not informed about the groups..

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Iran, Arak, Sardasht, Basij Square, near Amiral-Momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-05-08, 1399/02/19

Ethics committee reference number

IR.ARAKMU.REC.1399.026

Health conditions studied

1

Description of health condition studied

Diabetic patients with impaired lipid profile

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

Primary outcomes

1

Description

Improving blood LDL

Timepoint

Measurement of blood LDL in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood LDL using biochemical kits.

2

Description

Improving blood HDL

Timepoint

Measurement of blood HDL in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood HDL using biochemical kits.

3

Description

Improving total cholesterol

Timepoint

Measurement of total cholesterol in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring total cholesterol using biochemical kits.

4

Description

Improving blood triglycerides

Timepoint

Measurement of blood triglycerides in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood triglycerides using biochemical kits.

5

Description

Improving blood VLDL

Timepoint

Measurement of blood VLDL in the beginning of the study (before the start of the study) and 6 weeks after the intervention

Method of measurement

Measuring blood VLDL using biochemical kits.

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention and 6 weeks after the intervention

Method of measurement

Scales

2

Description

BMI

Timepoint

Before the intervention and 6 weeks after the intervention

Method of measurement

Weight (kg) / height (meters) to the power of 2

Intervention groups

1

Description

Intervention group: This group received 3 diabetic capsules (500 mg) daily for 6 weeks. Diabetes capsule consists of three plant components (Rhus corindria, Trigonella Foenum and Portulaca Oleracea). This capsule is made by Sanabel Drug Company.

Category

Treatment - Drugs

2

Description

Control group: This group received 3 placebo capsules (500 mg) daily for 6 weeks. This capsule is made by Sanabel Drug Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Clinic

Full name of responsible person

Mehdi Salehi

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Imam Street, Kowsar Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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

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Alireza Niknafs

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PhD student

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable