

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of viabet capsule, a herbal formulation, as an adjuvant treatment for diabetes mellitus type 2

Protocol summary

Study aim

Evaluation of the efficacy of viabet capsule as adjunctive therapy in the treatment of type 2 diabetes

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

The study will be conducted on patients referred to Ghaem Hospital in Mashhad. In this study, patients, treating physician, pharmacy student, and clinical pharmacist will be blinded to which patient receives the drug or placebo.

Participants/Inclusion and exclusion criteria

inclusion Type 2 diabetes according to the 2019 ADA Guideline; Only take metformin tablets; BMI between 25 - 32 Exclusion Pregnancy and lactation; Sensitivity to drug; Taking other diabetes; medications except metformin; taking drugs that affect blood sugar such as glucocorticoids; Other serious illnesses such as heart failure; Stomach or duodenal ulcer; Use of anticoagulants such as heparin

Intervention groups

Viabet 500mg capsule three times daily in the intervention group and placebo capsule; Contains all ingredients in capsule viabet except active ingredients three times a day for three months

Main outcome variables

weight; FBS and HbA1c; blood pressure; Fat and liver profile; creatinine and BUN; Possible side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045124N1**

Registration date: **2020-02-17, 1398/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-17, 1398/11/28**

Update count: **0**

Registration date

2020-02-17, 1398/11/28

Registrant information

Name

Omid Tanzifi roodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5423 1891

Email address

tasnifio931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-07, 1398/10/17

Expected recruitment end date

2020-05-18, 1399/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of viabet capsule, a herbal formulation, as an adjuvant treatment for diabetes mellitus type 2

Public title

Evaluation of viabet capsule, a herbal formulation, as an adjuvant treatment for diabetes mellitus type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes according to the 2019 ADA Guideline
Only take metformin tablets BMI between 25 - 32

Exclusion criteria:

Pregnancy and lactation Sensitivity to drug Taking other diabetes medications except metformin taking drugs that affect blood sugar such as glucocorticoids Other serious illnesses such as heart failure Stomach or duodenal ulcer Use of anticoagulants such as heparin

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

With the help of a randomization list provided by randomization.com site, patients will receive code 1 or 2 and will be included in placebo or medication group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The viabet and placebo formulations will be packaged by the manufacturer in identical-looking bottle and delivered to medicine specialist. Patients who meet the inclusion criteria are selected by medicine specialist to be included in the study, randomly assigned to a drug or placebo group and given a bottle with A or B mark. Patients will be evaluated in the course of treatment by an medicine specialist and a pharmacy student. Data collection and analysis are performed by the pharmacy student and clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences

Street address

daneshgah street; Qureshi Building

City

mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2019-10-02, 1398/07/10

Ethics committee reference number

IR.MUMS.REC.1398.192

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

Starting Study; One month later; Two months later; End of study

Method of measurement

Measurement of serum level in the laboratory

2

Description

Hemoglobin A1C

Timepoint

Starting Study; End of study

Method of measurement

Measurement of serum level in the laboratory

Secondary outcomes

1

Description

Serum creatinine

Timepoint

starting Study; End of study

Method of measurement

Measurement of serum level in the laboratory

2

Description

Blood Urea Nitrogen

Timepoint

starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

3

Description
Aspartate aminotransferase
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

4

Description
Alanine aminotransferase
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

5

Description
Triglyceride
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

6

Description
Cholesterol
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

7

Description
Low-density lipoprotein
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

8

Description
High-density lipoprotein
Timepoint
starting Study; End of study
Method of measurement
Measurement of serum level in the laboratory

9

Description
Weight
Timepoint
Starting Study; One month later; Two months later; End

of study
Method of measurement
by scale

10

Description
Blood pressure
Timepoint
Starting Study; One month later; Two months later; End of study
Method of measurement
By manometer

Intervention groups

1

Description
Intervention group: viabet 500 mg three times a day for 3 months
Category
Treatment - Drugs

2

Description
Control group: viabet placebo three times a day for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital of Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Street address
Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1588
Email
elyasis@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

City

Mashhad

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Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1337

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Pharmaceutical Company Essential Oil Dr Soleimani

Full name of responsible person

Ala Soleimani

Street address

Valiasr Aven.

City

Gorgan

Province

Golestan

Postal code

09117018040

Phone

+98 17 3233 9999

Email

giahessence@gmail.com

Web page address

<https://www.giahessence.com/fa-IR>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Company Essential Oil Dr Soleimani

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Omid Tanzifi Roodi

Position

دانشجوی دکتری عمومی داروسازی

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

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Email

tasnifo9331@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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City

Mashhad

Province

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Postal code

17871 91886

Phone

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Email

elyasis@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Omid tanzifi roodi

Position

دانشجوی دکتری عمومی داروسازی

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

tasnifio931@mums.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information will be published as an article

When the data will become available and for how long

The article will be available through Infinite Journal

To whom data/document is available

Anyone who needs them can access

Under which criteria data/document could be used

The data not published in this article will be provided in coordination with all project partners and research assistants of Mashhad University of Medical Sciences

From where data/document is obtainable

Send an Email to Scientific Officer

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

The consent of all research associates of Mashhad University of Medical Sciences should be obtained

Comments