

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of herbal klatin capsule on laboratory indices and quality of life in type 2 diabetes patients

Protocol summary

Registration timing: **prospective**

Study aim

To determine the effect of klatin (*Glaucium flavum*) in the glycaemic control in diabetes patients

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 66 patients with blocked randomization

Registration date

2022-01-18, 1400/10/28

Settings and conduct

This study will be performed on 66 type 2 diabetic patients who refer to specialized endocrinology clinics in Sari, including Touba Clinic and Imam Khomeini Hospital in Sari, after applying the conditions of entry and exit from the study and completing the informed consent form with random blocking are placed in one of the intervention and control groups.

Registrant information

Name

Ghorban Deyri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3324 3117

Email address

drdeyri41@gmail.com

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Having type 2 diabetes for at least three months prior to enrollment Adults over 18 years Inclusion criteria: Pregnancy and lactation History of liver and kidney diseases

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group: Patients take their oral diabetes medications without any changes and in addition, they receive oral herbal capsules contain 1000 mg of herbal klatin extract three times a day for 60 days Control group: Patients take their oral diabetes medications without any changes and in addition, they receive placebo 1000 mg capsules (microcrystalline cellulose) three times a day for 60 days.

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

2022-02-19, 1400/11/30

Actual recruitment end date

2023-02-19, 1401/11/30

Trial completion date

2023-02-19, 1401/11/30

Main outcome variables

Fasting blood sugar, Hg A1C

Scientific title

Evaluation of the effect of herbal klatin capsule on laboratory indices and quality of life in type 2 diabetes patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210724051965N1**

Registration date: **2022-01-18, 1400/10/28**

Public title

The effect of klatin capsule on type 2 diabetes

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having type 2 diabetes at least three months before enrollment Adults over 18 years
Exclusion criteria:
Pregnancy lactation kidney disease liver disease

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**
Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be randomly assigned to experimental and control groups using the size 4 random block method. For random assignment, each group will be considered as 4 people in 4 modes and therefore 6 different modes can occur: AABB-ABAB-ABBA-BAAB-BABA-BBAA. The number of people in each group is equal and this is repeated for 66 patients. According to the above block, 66 envelopes are prepared and A or B are placed in each envelope and numbers 1 to 66 are written on the envelopes. Someone outside the research team puts the letters A and B in the envelopes. A or B each represent the intervention or control group, which determines the type of intervention and A or B being a statistician.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mazandaran University of Medical Sciences

Street address

Moallem square, Moallem avenue

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2021-11-03, 1400/08/12

Ethics committee reference number

IR.MAZUMS.REC.1400.544

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning of the study (before the intervention) and 60 days after intervention

Method of measurement

Biochemistry- Glucose oxidase (enzymatic method)

2

Description

Hemoglobin A1c

Timepoint

At the beginning of the study (before the intervention) and 60 days after intervention

Method of measurement

Biochemistry- Calorimetry

3

Description

Cholesterol

Timepoint

At the beginning of the study (before the intervention) and 60 days after intervention

Method of measurement

Calorimetric enzymatic

4

Description

Triglyceride

Timepoint

At the beginning of the study (before the intervention) and 60 days after intervention

Method of measurement

Calorimetric enzymatic

Secondary outcomes

1

Description

Blood creatinine

Timepoint

Before the intervention and 60 days after the intervention

Method of measurement

Enzymatic

2

Description

Blood urea nitrogen

Timepoint

Before the intervention and 60 days after the intervention

Method of measurement

Calorimetric enzymatic

3

Description

Quality of Life

Timepoint

Before the intervention and 60 days after the intervention

Method of measurement

Quality of Life Assessment Questionnaire 15 questions for patients with diabetes

Intervention groups

1

Description

Intervention group: In this group patients take their oral diabetes medications without any changes and in addition, they received klatin capsule (Contains 1000 mg of klatin plant extract of Plasma Darman Sarve Sepid Company) three times a day for 60 days.

Category

Treatment - Drugs

2

Description

Control group (placebo): In this group patients take their oral diabetes medications without any changes and in addition, they receive placebo (capsule containing 1000 mg microcrystalline cellulose of Plasma Darman Sarve Sepid Company) three times a day for 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari city

Full name of responsible person

Sedighe Yousefi

Street address

Center for Traditional Medicine and Complementary Medicine of Mazandaran University; Khazar Boulevard, Khazar Square of Sari

City

Sari

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Phone

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2

Recruitment center

Name of recruitment center

Touba Center of Mazandaran University of Medical Sciences

Full name of responsible person

Ghorban Deyri

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Khazar Boulevard; Khazar Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saidi

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Sedighe Yousefi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Other areas of specialty/work

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

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Full name of responsible person

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P.h.D student

Latest degree

Medical doctor

Other areas of specialty/work

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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