Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
To determine the effect of klatin (Glaucium flavum) in the glycaemic control in diabetes patients
Design
Clinical trial with control group, double-blind, randomized, phase 3 on 66 patients with blocked randomization
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.
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
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.
Main outcome variables
Fasting blood sugar، Hg A1C

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210724051965N1**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **prospective**

Last update: **2022-01-18, 1400/10/28**
Update count: **0**
Registration date
2022-01-18, 1400/10/28

Registrant information
Name
Ghorban Deyri
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

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

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

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 envelops. 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

Fating 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

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2

Recruitment center

Name of recruitment center

Touba Center of Mazandaran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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
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Assistant professor
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Person responsible for updating data

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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