

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of Hibiscus esculentus on blood sugar and lipids of patients with type 2 Diabetes: A double blind clinical trial

Protocol summary

Study aim

Determining the effect of Hibiscus esculentus plant on blood sugar, hepatic and lipid profiles and insulin resistance in patients with diabetic type two

Design

This study is a multi-center double-blinded randomized control trial with placebo which is done on 66 patients with type two diabetic who refer endocrine disease clinics affiliated to Mazandaran University of Medical Sciences in Sari city.

Settings and conduct

The filed of the study includes the endocrine disease clinics affiliated to Mazandaran University of Medical Sciences in Sari city.

Participants/Inclusion and exclusion criteria

The study inclusion criteria include having type 2 diabetes at least three months before entering the study, Age between 20 and 80 years, Hemoglobin A1C more than 7.5 at time of entering the study. The exclusion criteria include unwillingness of the patient, obeying a diet regimen or special kind of exercise and known allergy to Hibiscus esculentus.

Intervention groups

The intervention and control groups use oral Hibiscus esculentus and placebo capsules respectively with the amount of two capsules three times in a day after breakfast, lunch, and dinner (6 capsules in total daily).

Main outcome variables

Fasting Blood Sugar, Hemoglobin A1c

General information

Reason for update

Acronym

EHBSLD

IRCT registration information

IRCT registration number: **IRCT20180609040020N1**

Registration date: **2018-06-15, 1397/03/25**

Registration timing: **prospective**

Last update: **2018-06-15, 1397/03/25**

Update count: **0**

Registration date

2018-06-15, 1397/03/25

Registrant information

Name

Ali Hesamzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-07, 1397/04/16

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Hibiscus esculentus on blood sugar and lipids of patients with type 2 Diabetes: A double blind clinical trial

Public title

Effect of Hibiscus esculentus on blood sugar and lipids of Type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Having type 2 diabetes at least three months before entering the study
 Age between 20 and 80 years
 Hemoglobin A1C more than 7.5 at time of entering the study
 Using a contraceptive method in women during reproductive age who entered the study

Exclusion criteria:
 Unwillingness of the patient
 Having known Immune deficiency
 Pregnancy and breastfeeding
 Obeying a diet regimen or especial kind of exercise
 Using supplements containing Hibiscus esculentus
 Cardiovascular diseases
 History of hepatic and renal diseases
 Uncontrolled thyroid disease
 History of diabetic ketoacidosis
 Creatinine more than 2
 Using drugs that have an effect on blood sugar level including Corticosteroids and thiazides
 Known allergy to Hibiscus esculentus plant
 Manifestation of acute physical problems during the intervention
 Changing the type of treatment and manifestation of hypoglycemia symptoms
 Severe Weight loss at least 10 percent during the past 6 months

Age
 From **20 years** old to **80 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
 Target sample size: **66**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomized block design

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Patients are randomly assigned to two groups of intervention and control based on randomized block design. For the randomized assignment, each group is considered 4 persons in 4 conditions, therefore 6 conditions may happen: AAB-B-ABAB-ABBA-BAAB-BABA-BBAA. The type of being intervention or control of A or B is determined by the statistical consultant. The color of capsules is similar for intervention and control group and the patients, clinical and outcome evaluators are unaware of the contents of the capsules and the way of patients' assignment into two groups of intervention and control.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Razi St.

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1397.1211

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

At the beginning of the intervention and at the end of intervention on the day 60

Method of measurement

Blood test

Secondary outcomes

1

Description

Hemoglobin A1C

Timepoint

En At the beginning of the intervention and at the end of intervention on the day 60

Method of measurement

Blood test

2

Description

Cholesterol

Timepoint

At the beginning of the intervention and at the end of intervention on the day 60

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group: Type 2 diabetic patients who use powder of Hibiscus esculentus with the dose of 1000 milligrams three times daily before breakfast, lunch, and dinner for 60 days.

Category

Treatment - Drugs

2

Description

Control group: Type 2 diabetic patients who use two placebo capsules three times daily before breakfast, lunch, and dinner for 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba clinic

Full name of responsible person

Ali Hesamzadeh

Street address

Khazar Blvd.

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Web page address

2

Recruitment center

Name of recruitment center

Imam Hospital clinic

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

Sari 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

Ali Hesamzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant Professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

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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 not more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available