Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Fenugreek, Cranberries, Chicory and Nettle seed extract on blood glucose in type 2 diabetic patients

Protocol summary

Study aim
A new drug discovery and a lower financial bug for patients with type 2 diabetes.The definition of a new herbal medicine is due to traditional treatments that are more consistent with indigenous culture. Localize the treatment of type 2 diabetes and discover less complicated drugs.

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

Settings and conduct
The study is conducted in Baqiyatallah Hospital, a tertiary care hospital, in 2017-2018. Lab Tests were calculated before and after study.The level of FBS is checked by the participant by the glucometer at home, daily for 3 days, then 2 days once for 4 days, then on days 15, 30, 45 and 60 and the numbers obtained are recorded in certain forms. Patients will be started at the beginning of the study. At the end of the study, FBS, Lipid profile, BUN, SGOT, SGPT, ALP, HbA1C, Creatinine will be performed. In order to ensure the health of the herbal medicine, liver and kidney function tests for the first and second months are also examined. Patients and investigator were blinded.

Participants/Inclusion and exclusion criteria
Non-insulin-dependent diabetes mellitus treated with a diet or oral medication, Not history of any disease, Non-pregnancy and breastfeeding,The occurrence of any unwanted adverse drug reaction in the requested serial tests and any unwanted gastrointestinal complications and the unwillingness of the participants to continue the study are the main exclusion criteria.

Intervention groups
Patients will receive 2, 1000 mg capsules twice daily containing one quarter of the effective dose of herbs, morning and night after the meal for three months. The control group, the same as the first group, the intervention and the placebo were similar to the treatment with rusks bread powder, which will be in two capsules of 1000 mg.

Main outcome variables
FBS, LFT, kidney function tests

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190112042332N1**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **retrospective**

Last update: **2019-01-26, 1397/11/06**
Update count: **0**

Registration date
2019-01-26, 1397/11/06

Registrant information

Name
Khalil Mohamdzadeh

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
2017-09-23, 1396/07/01

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Fenugreek, Cranberries, Chicory and Nettle seed extract on blood glucose in type 2 diabetic patients

Public title

Effect of Fenugreek, Cranberries, Chicory and Nettle seed extracts on blood glucose in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female subjects between 20 and 70 years of age Noninsulin-dependent diabetes minimum of 2 years before the study enrollment Patients with diabetes Type 2 and on any antidiabetic medication (oral hypoglycemic agent, insulin) Patients willing to give informed consent Patients with out other comorbid conditions (cardiac, renal, macrovascular and microvascular complication) Non Gangren's diabetic foot ulcer Not Currently pregnant or breastfeeding, fertile women with out using any contraceptives methods Current daily tobacco smoker and Alcohol consumption with out any decision to change diet and physical style Not having a history of cancer less than 5 years and a depression

Exclusion criteria:

Evidence of any unwanted side effects of the drug include increased liver enzymes or functional renal dysfunction or Lower blood glucose control in the requested serial tests Evidence of any unwanted gastrointestinal discomfort, such as diarrhea, nausea, or gastrointestinal intolerance of the combined medication Any unwillingness of participants to continue to participate in the plan

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Treatment assignment is randomly assigned, in a 1:1 ratio, at each site using a block size of 6. Herbal and placebo medicines are packed in packages that are quite similar to those labeled A and B.To select patients, each patient should first receive a number from 1 to 100 (total sample size) given randomized visits to patients from closed medicines.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment assignments are known to the study coordinator. Participants, treating clinicians, and outcome assessors are blinded to intervention group status.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Mullasadra Street,Vanak Square,Tehran

City

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Province

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Postal code

548719395

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.BMSU.REC.1394.87

Health conditions studied

1

Description of health condition studied

Blood Glucose Control in Type 2 Diabetic patients

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Glucose

Timepoint

Before, at the first of study, daily for 3 days, once 2days for 4 days , on the days of 15, 30, 45 and 60

Method of measurement

patients with check fasting blood glucose with Glucometer at Home

Secondary outcomes

1

Description
Liver Function Test
Timepoint
Before, After, At the end of first month, At the end of second month
Method of measurement
Liver Function Tests

Intervention groups

1

Description
Intervention group: Two Capsule containing one fourth of the effective dose of four medicinal herbs
Category
Treatment - Drugs

2

Description
Control group: Two Capsule containing Rye bread powder, 1000 mg twice a day, morning and night after meals
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Khalil Mohamadzadeh
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Sponsors / Funding sources

1

Sponsor
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
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Khalil Mohamadzadeh
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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