Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Silybum marianum, Melissa officinalis, Vaccinium arctostaphylos, Trigonella foenum, Urtica dioica, and Citrullus colocynthis extract mixture on blood sugar control in type 2 diabetic patients

Protocol summary

Study aim
Effect of herbal extract mixture Silybum marianum, Melissa officinalis, Vaccinium arctostaphylos, Trigonella foenum, Urtica dioica, and Citrullus colocynthis on blood sugar control in type 2 diabetic patients

Design
This double-blind, phase 2 clinical trial is performed in 60 type II diabetic patients divided equally in herbal and placebo groups. The herbal drug and placebo with code A or B who no one except laboratory expert aware of its contents are prescribed to patients for 3 months.

Settings and conduct
The type 2 diabetic patients referring to Baghiatallah Hospital according to inclusion criteria randomly divided three groups. After selection the patients are given any of herbal drug or placebo capsule boxes by nurse with an identification code of A or B which are recorded in the patient's medical records. Physician, nurse, patients, data collector and who evaluate the outcome are unaware of the drug and placebo group. Only laboratory expert knows the types of the groups. Patients are aware that they are either in the herbal drug or placebo groups, but they are not aware of the type of group they are in.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type II diabetic patients; 40 to 60 years old; fasting blood glucose levels 130 to170 mg/dL; glycosylated hemoglobin 7.5 to 8.5% Exclusion criteria: Patients with a diabetic foot ulcer, gangrene or any severe illness and who tend to change their exercise program or diet

Intervention groups
Intervention group: Patients in this group receive a 500 mg capsule of herbal drug twice a day after breakfast. Placebo group: Patients in this group receive a 500 mg capsule of placebo twice a day after breakfast.

Main outcome variables
Fasting blood glucose and glycosylated hemoglobin levels are determined at baseline and after three months as a main outcome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001157N15**
Registration date: **2019-08-01, 1398/05/10**
Registration timing: **prospective**

Last update: **2019-08-01, 1398/05/10**
Update count: **0**

Registration date
2019-08-01, 1398/05/10

Registrant information

Name
Hasan Fallah Huseini

Name of organization / entity
Institute of Medicinal Plants

Country
Iran (Islamic Republic of)

Phone
+98 26 3476 4010

Email address
fallah@imp.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Silybum marianum, Melissa officinalis, Vaccinium arctostaphylos, Trigonella foenum, Urtica dioica, and Citrullus colocynthis extract mixture on blood sugar control in type 2 diabetic patients

Public title
Effect of Silybum marianum, Melissa officinalis, Vaccinium arctostaphylos, Trigonella foenum, Urtica dioica, and Citrullus colocynthis extract mixture on blood sugar control in type 2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate type 2 diabetes 40 to 60 years old Have diabetes for at least two years Under treatment with a maximum daily dose of 1000 mg metformin and 10 mg glibenclamide Fasting blood glucose levels between 130 to 170 mg/dL Glycosylated hemoglobin between 7.5 to 8.5%
Exclusion criteria:
Patients with diabetic foot ulcer, gangrene, or any severe illness Painful diabetic neuropathy and depressed patients Smokers and alcoholic patients Patients who tend to change their exercise program or diet
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a random number table and block randomization method is used. In this method the patients are assigned into blocks of 2 patients (total 30 blocks). Then, each of the 2 patients entered the block of herbal drug or placebo, with 30 patients assigned to each group. There is no significant difference in fasting blood glucose and glycosylated hemoglobin in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Package for herbal and placebo is labeled with code B or A. Other specifications on the labels are identical. Physicians, nurses, patients, data collectors and those who evaluate the outcome are unaware of the drug and placebo group. Only laboratory expert knows the types of the groups. Patients are aware that they are either in the herbal drug or placebo groups, but they are not aware of the type of group they are in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Avicenna Research Institute
Street address
Shahid Beheshti University, Tabnak Street, Shahid Chamran Highway, Evin, Tehran. IRAN
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2019-07-02, 1398/04/11
Ethics committee reference number
IR.ACECR.AVICENNA.REC.1398.013

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood glucose level will be determined in laboratory by commercial standard kit

2

Description
Glycosylated hemoglobin
Timepoint
At starting of the study and after 3 months
Method of measurement
Glycosylated hemoglobin will be determined in laboratory by commercial standard kit

Secondary outcomes

1

Description
Triglyceride
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood triglyceride level will be determined in laboratory by commercially available kit

2

Description
Cholesterol
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood cholesterol level will be determined in laboratory by commercially available kit

3

Description
low-density lipoprotein
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood low-density lipoprotein level will be determined in laboratory by commercially available kit

4

Description
High-density lipoprotein
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood High-density lipoprotein level will be determined in laboratory by commercially available kit

5

Description
Aspartate aminotransferase
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood aspartate aminotransferase level will be determined in laboratory by commercially available kit

6

Description
Alanine aminotransferase
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood alanine aminotransferase level will be determined in laboratory by commercially available kit

7

Description
Blood urea nitrogen
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood blood urea nitrogen level will be determined in laboratory by commercially available kit

8

Description
Creatinine
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood creatinine level will be determined in laboratory by commercially available kit

9

Description
Alkalin phosphatase
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood Alkalin phosphatase level will be determined in laboratory by commercially available kit

Intervention groups

1

Description
Intervention group: Patients in this group receive a 500 mg capsule of herbal drug twice a day after breakfast.The herbal drug capsule contains mixture of mentioned herbal extract powder and will be prepared in the pharmacognosy department of the Institute of Medicinal Plants, Jahad-e-daneshgahi.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive a 500 mg capsule of placebo twice a day after breakfast.The placebo capsule contains toasted flour and will be prepared in the pharmacognosy department of the Institute of Medicinal Plants, Jahad-e-daneshgahi.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah University of Medical Sciences

Full name of responsible person
Reza Mohtashami

Street address
Vanak square, Molasadra Ave

City
Tehran

Province
Tehran

Postal code
1484958693

Phone
+98 21 8806 8923

Fax
+98 21 8806 8923

Email
rmohtashami@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Reza Hajiaghaee

Street address
Institute of Medicinal Plants, Kavosh Blvd., Supa Blvd., Poleh Kordan

City
Tehran

Province
Tehran

Postal code
3365166571

Phone
+98 26 3476 4010

Fax
+98 26 3476 4021

Email
rhajiaghaee@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Iranian academic center for education culture and research

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
Iranian academic center for education culture and research

Full name of responsible person
Hasan Fallah Huseini

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Institute of Medicinal Plants, Kavosh Blvd., Supa Blvd., Poleh Kordan

City
Tehran

Province
Tehran

Postal code
3365166571

Phone
+98 26 3476 4010

Fax
+98 26 3476 4021

Email
h.fallah@acecr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Hasan Fallah Huseini

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Fax
+98 26 3476 4021

Email
h.fallah@acecr.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Hasan Fallah Huseini

Position
Associate professor

Latest degree
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Phone
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Fax
+98 26 3476 4010

Email
h.fallah@acecr.ac.ir

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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available