Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of antidiabetic effect of Abelmoschus culentesus (Okra) on diabetes mellitus type 2 patients who received oral agents

Protocol summary

Study aim

Improve patients blood glucose control with oral agents and reduce Insulin requirement in patients with type 2 diabetes

Design

The double-blind, randomized, placebo-controlled trial with a parallel group design of 128 patients, enrolled between June 2018 and December 2018, and followed for two months.

Settings and conduct

Diabetes, outpatient clinic for diabetes,Tabriz, Iran, double blind 128 patients due to the inclusion and exclusion criteria will involve in this study. Patients will divided into two groups (64 in each). for all patients Okra (as an intervention) or cellulose (as a placebo) capsule 750 mg, two capsule every 6 hours, 30 minutes before meal for two months will be administered depend on each randomized group (intervention or placebo). At baseline and after two months Hemoglobin a1c, Fasting Blood Sugar, lipid profile and weight will be assessed.

Participants/Inclusion and exclusion criteria

1- All patients older than 18 years with diabetes mellitus type 2 2- Patients who received oral agents (metformin, sulfonylurea, pioglitazone)

Intervention groups

Intervention group: Okra capsule 750 mg, two capsule every 6 hours, 30 minutes before meal for two months will be administered for patients who randomized to this group. Placebo group: cellulose capsule 750 mg, two capsule every 6 hours, 30 minutes before meal for two months will be administered for patients who randomized to this group. The blood sample will be taken at baseline and after two months of intervention for all patients.

Main outcome variables

Reduce the level of fasting blood sugar and hemoglobin A1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160310026998N8**
Registration date: **2018-07-13, 1397/04/22**
Registration timing: **prospective**

Last update: **2018-07-13, 1397/04/22**
Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name
Saba Ghaffary
Name of organization / entity
Faculty of Pharmacy, Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 33266042
Email address
ghaffarys@tbzmed.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-04-21, 2018/02/01

Expected recruitment end date

2640-04-19, 2019/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of antidiabetic effect of Abelmoschus culentesus (Okra) on diabetes mellitus type 2 patients who received oral agents

Public title
Effects of Okra on blood glucose of patients with diabetes mellitus type 2
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients older than 18 years with diabetes mellitus type 2 who received oral agents (metformin/sulfonylureas/pioglitazone)
Exclusion criteria:
pregnancy and lactation creatinine clearance less than 30 ml/min severe hepatic impairment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization: Simple randomization, the computer generates 128 digits by excel which divided them in two groups A and B randomly.The researcher will allocated patients in each of groups A and B by the patients show up from 1 to 128.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients do not aware of being in intervention or placebo groups. Physician does not any information about randomization and groups of patients. Statistician will not aware of intervention and placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee at Tabriz University of Medical Sciences
Street address
Faculty pf pharmacy, Tabriz University of Medical Sciences, Shahid ghazi hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2018-03-11, 1396/12/20
Ethics committee reference number
IR.TBZMED.REC.1396.1268

Health conditions studied

1

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

Primary outcomes

1

Description
Reduce the fasting blood sugar
Timepoint
At baseline and two months after intervention
Method of measurement
Blood sample analysis

2

Description
Hemoglobin a1c
Timepoint
At baseline and two months after intervention
Method of measurement
Blood sample analysis

Secondary outcomes

1

Description
Reduce of low density lipoprotein (LDL)
Timepoint
At baseline and two months after intervention
Method of measurement
Blood sample analysis

2

Description
Weight loss
Timepoint

At baseline and two months after intervention
Method of measurement
scale

3

Description
Reduce triglycerides
Timepoint
At baseline and two months after intervention
Method of measurement
Blood sample analysis

Intervention groups

1

Description
Intervention group: Okra capsule 750 mg, two capsule every 6 hours, 30 minutes before meal for two months
Category
Treatment - Drugs

2

Description
Control group: placebo capsule contains cellulose 750 mg, two capsule every 6 hours, 30 minutes before meal for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
outpatient clinic of Dr. Aghamohammad zadeh
Full name of responsible person
Saba Ghaffary
Street address
Daneshgah square, outpatient clinic of Dr. Aghamohammad zadeh
City
Tabriz
Province
East Azarbaijan
Postal code
14766 - 51664
Phone
+98 41 3336 5010
Email
ghaffarys@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Saba Ghaffary
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street,Tabriz , Iran
City
Tabriz
Province
East Azarbaijan
Postal code
14766 - 51664
Phone
+98 41 3336 5010
Email
ghaffarys@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Saba Ghaffary
Position
Assistant Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
faculty of pharmacy, Assistant Professor of Clinical Pharmacy
City
Tabriz
Province
East Azarbaijan
Postal code
14766 - 51664
Phone
+41 33365010
Fax
Email
ghaffarys@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Saba Ghaffary

Position
Assistant Professor of Clinical Pharmacy

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
faculty of pharmacy, Assistant Professor of Clinical Pharmacy

City
Tabriz

Province
East Azarbaijan

Postal code
14766 - 51664

Phone
+41 33365010

Fax

Email
ghaffarys@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Saba Ghaffary

Position
Assistant Professor of Clinical Pharmacy

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
faculty of pharmacy, Assistant Professor of Clinical Pharmacy

City
Tabriz

Province
East Azarbaijan

Postal code
14766 - 51664

Phone
+41 33365010

Fax

Email
ghaffarys@tbzmed.ac.ir

Web page address

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