Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of therapeutic effect of Cichorium intybus in patients with type 2 diabetes: a randomized double blind clinical trial

Protocol summary

Study aim

To investigate therapeutic effect of whole chicory plant powder in type 2 diabetic patients

Design

90 eligible patients referring to Shahid-Mohammadi Diabetes clinic will be entered in this phase 3 clinical trial. They will be randomly assigned into two groups of placebo and intervention. Group allocation will concealed by assigning a unique code to each participant and participants will receive powders in capsules.

Settings and conduct

This research will be conducted in Shahid-Mohammadi Diabetes clinic (Bandar Abbas, Iran) and participants will receive capsules in the clinic. They should take them two times a day (3 cap after breakfast and dinner) for 3 months (each capsule contains 500 mg herbal powder or Maltodextrin). All participants, administrators and data collectors will be blinded.

Participants/Inclusion and exclusion criteria

inclusion: 1. patients with type 2 diabetes (T2DM) 2. age: 30 to 65 years 3. BMI< 30kg / m ^ 2 4. Diagnosed for diabetes for at least one year 5. Taking anti-diabetes drugs 6. not using insulin exclusion: 1. Addiction to alcohol and drugs 2. Abnormal level of liver enzymes or BUN or creatinine 3. Any change in the type, or dosage of antidiabetic drugs or administration of insulin 4. The presence of special diseases or conditions (eg, nephropathy, thyroid disease, pregnancy, etc.) 5. Taking medications that affect blood sugar levels 6. Failure to follow the study protocol

Intervention groups

This research includes two groups: intervention group who will receive capsules containing chicory powder and placebo group who will receive capsules containing Maltodextrin. This research was designed to evaluate therapeutic effect of chicory in patients with type 2 diabetes in comparison with Maltodextrin as placebo.

Main outcome variables

Fasting Blood Glucose (FBC)؛ Hemoglobin A1c (HbA1c)؛ Homeostatic Model Assessment of Insulin Resistance (HOMAIR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171220037971N1**
Registration date: **2018-05-09, 1397/02/19**
Registration timing: **prospective**

Last update: **2018-05-09, 1397/02/19**
Update count: **0**

Registration date

2018-05-09, 1397/02/19

Registrant information

Name

Kambiz Rostamizadetelzali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0405

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krostamizade@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effect of Cichorium intybus in patients with type 2 diabetes: a randomized double blind clinical trial

Public title
Therapeutic effect of chicory in type 2 diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with type 2 diabetes (T2DM) age from 30 to 65 years BMI less than 30kg / m ^ 2 They have been diagnosed for diabetes at least one year before entering into the study Taking anti-diabetes drugs (the type of medicine is not a criterion) not using insulin

Exclusion criteria:
Addiction to alcohol and drugs Abnormal level of liver enzymes or BUN or creatinine Any change in the type, or dosage of antidiabetic drugs or administration of insulin The presence of special diseases or condition (eg, nephropathy, thyroid disease, pregnancy, etc.) Taking medications that affect blood sugar levels Failure to follow the study protocol

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive chicory (powder of whole plant within capsules) and the other will receive placebo (Maltodextrin within capsules). The participants and administrator do not have any information about content of capsules (double blinded study).

Blinding (investigator's opinion)
Double blinded

Blinding description
The identical capsules will be separated into 2 groups by corresponding author: group 1 and group 2. Just the corresponding author knows about content of the capsules, and during the intervention period she doesn't have any contact with participants or administrators. The persons who collect data don't have any information about content of the capsules. Participants do not have any information about content of the capsules because the shape and color of capsules are identical. All analyses will be performed just using codes: group 1 and 2. At the end of assessment the contents of capsules will be revealed by the corresponding author.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Payambar Aazam Medical and Educational complex, Kuy e Farhangiyan, Bandar Abbas, Hormozgan Province

City
Bandar-abbas

Province
Hormozgan

Postal code
7919915519

Approval date
2018-04-29, 1397/02/09

Ethics committee reference number
IR.HUMS.REC.1397.017

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
fasting blood glucose

Timepoint
investigate fasting blood glucose at the first and end of research

Method of measurement
Autoanalyzer spectrophotometer

2

Description
Hemoglobin A1c
Timepoint
investigate Hemoglobin A1c at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

3

Description
Homeostatic Model Assessment of Insulin Resistance
Timepoint
investigate Homeostatic Model Assessment of Insulin Resistance at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

Secondary outcomes

1

Description
serum level of triglyceride
Timepoint
investigate serum level of triglyceride at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

2

Description
serum level of total cholesterol
Timepoint
investigate serum level of total cholesterol at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

3

Description
serum level of low density lipoprotein cholesterol
Timepoint
investigate serum level of low density lipoprotein cholesterol at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

4

Description
serum level of high density lipoprotein cholesterol
Timepoint
investigate serum level of high density lipoprotein cholesterol at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

5

Description
serum level of Aspartate Aminotransferase
Timepoint
investigate serum level of Aspartate Aminotransferase at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

6

Description
serum level of Alanine Aminotransferase
Timepoint
investigate serum level of Alanine Aminotransferase at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

7

Description
serum level of alkaline phosphatase
Timepoint
investigate serum level of alkaline phosphatase at the first and end of research
Method of measurement
Autoanalyzer spectrophotometer

8

Description
blood pressure
Timepoint
investigate blood pressure at the first and end of research
Method of measurement
The mercury manometer

Intervention groups

1

Description
Intervention group: The intervention group in this research will receive whole chicory plant powder. Participants take 3 gr chicory powder daily as 6 capsules and take them 2 times a day after breakfast and dinner. This herb will be bought and packaged in Tehran Faculty of Pharmacy.
Category
Treatment - Drugs

2

Description
Control group: The placebo group in this research will receive Maltodextrin. Participants take 3 gr Maltodextrin daily as 6 capsules and take them 2 times a day after breakfast and dinner. This compound will be Bought and packaged in Tehran Faculty of Pharmacy.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohammadi hospital

Full name of responsible person
Fatemeh Hendijani

Street address
Payambar aazam medical and educational complex, Kuy e Farhangiyan, Bandar Abbas, Hormozgan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Fatemeh Hendijani

Street address
Hormozgan University of Medical Sciences, Shahid Chamran Blvd, Bandar abbas, Hormozgan, Iran

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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Fatemeh Hendijani

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutical Biotechnology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Fatemeh Hendijani

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutical Biotechnology

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Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Kambiz Rostamizadetelzali

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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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 no more data 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
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