

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 be 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<sup>2</sup> 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 Rostamizadetalzali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3371 0405

##### Email address

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 <sup>2</sup> 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

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3334 7000

**Email**

shmh@hums.ac.ir

## 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

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Phone**

+98 76 3333 3280

**Email**

mail@hums.ac.ir

**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

**Street address**

Faculty of Pharmacy and Pharmaceutical Sciences,  
Opposite the Sports Club of Workers, Imam Hossein  
Blvd, Bandar abbas

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919691982

**Phone**

+98 76 3371 0405

**Email**

f\_hendijani@pharm.mui.ac.ir

## 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

**Street address**

Faculty of Pharmacy and Pharmaceutical Sciences,  
Opposite the Sports Club of Workers, Imam Hossein  
Blvd, Bandar abbas

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919691982

**Phone**

+98 76 3371 0405

**Email**

f\_hendijani@pharm.mui.ac.ir

## Person responsible for updating data

krostamizade@hums.ac.ir

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Kambiz Rostamizadetalzali

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy and Pharmaceutical Sciences,  
Opposite the Sports Club of Workers, Imam Hossein  
Blvd, Bandar abbas

**City**

Bandar abbas

**Province**

Hormozgan

**Postal code**

7919691982

**Phone**

+98 76 3371 0406

**Email**

## 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