

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of consumption of barberry fruit powder on glycemic indices , lipid profile and Visfatin in type 2 diabetic patients

Protocol summary

Study aim

The effect of consumption of barberry fruit powder on glycemic indices , lipid profile and Visfatin in type 2 diabetic patients

Design

Clinical trials with intervention and control group, with parallel groups, single blind, randomized

Settings and conduct

40 patients with type 2 diabetes who are referred to the diabetes clinic of Booali Hospital in Zahedan who are eligible to enter the study will be selected. The samples were randomly divided into two intervention groups (20 persons) and control group (20 people) by using case number. The intervention group received 1 g of barberry dried fruit powder (2 capsules of 500 mg) per serving (1 capsule with lunch and 1 capsule with dinner) daily, and the control group received placebo (a capsule containing lactose). All participants in the plan thought that they had received the intervention and that they were not known to be in the group receiving the barberry powder or the placebo group. The data analyst also stated that the data were from the consumer powder group Barberry or group receiving a placebo is unaware.

Participants/Inclusion and exclusion criteria

Entry requirements; All people with type 2 diabetes have been diagnosed, Use of fixed drugs during the intervention Conditions not enter; Insulin treatment

Intervention groups

The intervention group received 1 g of barberry dried fruit powder (2 capsules of 500 mg) per serving (1 capsule with lunch and 1 capsule with dinner) daily, and the control group received placebo (a capsule containing lactose).

Main outcome variables

Visfatin; Fasting blood sugar; Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180811040758N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **prospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Shadi Shourestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 3865

Email address

shadi.shourestani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of consumption of barberry fruit powder on glycemic indices , lipid profile and Visfatin in type 2 diabetic patients

Public title

The effect of consumption of barberry fruit powder in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with type 2 diabetes are diagnosed

Exclusion criteria:

Pregnancy Lactation History of heart disease History of heart failure in the last 3 months heart attack Acute and chronic hepatic disease, except fatty liver Impaired kidney function Hyperthyroidism and hypothyroidism Use of NSAIDs Insulin treatment Taking antidepressants

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly with the help of random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants in the plan thought that they had received the intervention and that they were not known to be in the group receiving the barberry powder or the placebo group. The data analyst also stated that the data were from the consumer powder group Barberry or group receiving a placebo is unaware.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan Medical Science Campus, Hesabi Square,

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.ZAUMS.REC.1397.201

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Fasting blood suger

Timepoint

Beginning of the intervention and 60 days after the intervention

Method of measurement

Measure with laboratory kit on blood sample

2**Description**

HbA1c

Timepoint

Beginning of the intervention and 60 days after the intervention

Method of measurement

Measure with laboratory kit on blood sample

3**Description**

Lipid profile

Timepoint

Beginning of the intervention and 60 days after the intervention

Method of measurement

Measure with laboratory kit on blood sample

4**Description**

Visfatin

Timepoint

Beginning of the intervention and 60 days after the intervention

Method of measurement

Measure with laboratory kit on blood sample

5

Description

Insulin

Timepoint

Beginning of the intervention and 60 days after the intervention

Method of measurement

Measure with laboratory kit on blood sample

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning of the intervention and 60 days after the intervention began

Method of measurement

Measure with laboratory kit on blood sample

2

Description

Hb A1c

Timepoint

At the beginning of the intervention and 60 days after the intervention began

Method of measurement

Measure with laboratory kit on blood sample

3

Description

Lipid profile

Timepoint

At the beginning of the intervention and 60 days after the intervention began

Method of measurement

Measure with laboratory kit on blood sample

4

Description

visfatin

Timepoint

At the beginning of the intervention and 60 days after the intervention began

Method of measurement

Measure with laboratory kit on blood sample

5

Description

Insulin

Timepoint

At the beginning of the intervention and 60 days after the intervention began

Method of measurement

Measure with laboratory kit on blood sample

Intervention groups

1

Description

Intervention group: The intervention group received 1 gram of powdered barberry dried fruit (2 capsules of 500mg) per serving for 2 months (1 capsule plus lunch and 1 capsule with dinner) for 2 months.

Category

Treatment - Other

2

Description

Control group: The control group received 1 g of placebo (2 capsules containing 500 mg of lactose) per day for 2 servings (1 capsule with lunch and 1 capsule with dinner) for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Buali Hospital in Zahedan

Full name of responsible person

Shadi Shourestani

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Buali Hospital, Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Shadi Shourestani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Associate Professor

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Person responsible for updating data

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Other areas of specialty/work

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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