

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of citrullus colocynthis fruit extract on blood sugar in type II diabetic patients: a double blind clinical trial

Protocol summary

Summary

80 type II diabetic patients aged between 30 to 60 years, with fasting blood glucose between 150-220 mg/dl and HbA1c 7.5-10% taking two metformin 500 mg or two glibenclamid 5 mg tablets daily, with minimum two year history of diabetes that not changed antidiabetic regimen before 3 months were selected. The patients signed the written informed consent and randomly allocated into C. colocynthis and placebo group. The patients will continue their standard anti-diabetic therapy without any change during the study. The patients in C. colocynthis group were treated by C. colocynthis capsules of 100 mg 3 times a day and other group with placebo capsule in same manner for 4 month. At end of the study the fasting blood glucose, glycosylated haemoglobin, cholesterol, LDL, HDL, triglyceride, aspartate aminotransferase, alanine aminotransferase and creatinine levels were measured in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010211984N1**

Registration date: **2014-07-03, 1393/04/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-03, 1393/04/12

Registrant information

Name

Maryam Yaghoobi

Name of organization / entity

Zahedan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Zahedan University Of Medical Sciences and Institute of Medicinal Plants, ACECR, Karaj, Iran

Expected recruitment start date

2012-12-26, 1391/10/06

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of citrullus colocynthis fruit extract on blood sugar in type II diabetic patients: a double blind clinical trial

Public title

Effect of citrullus colocynthis on Type II diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 30 to 60 years; fasting blood glucose between 180-220 mg/dl; HbA1c 7.5-9%; taking two metformin 500 mg or two glibenclamid 5 mg tablets daily; with minimum two year history of diabetes that not changed antidiabetic regimen before 3 months. Exclusion criteria: Insulin therapy; severe kidney, liver, cardiovascular and infectious disease; pregnant and breast feeding woman.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Daneshgah Ave. Dr. Hesabi square,

City

Zahedan

Postal code

16743463

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

1432

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Blood sugar

Timepoint

At baseline and after four months

Method of measurement

Fasting blood glucose was measured by commercial kit in laboratory

2

Description

Glycosylated haemoglobin

Timepoint

At baseline and after four months

Method of measurement

Blood HbA1C was determined in laboratory by commercially available kit

Secondary outcomes

1

Description

LDL

Timepoint

At baseline and after four months

Method of measurement

Blood LDL level was determined in laboratory by commercially available kit

2

Description

HDL

Timepoint

At baseline and after four months

Method of measurement

Blood HDL level was determined in laboratory by commercially available kit

3

Description

Cholesterol

Timepoint

At baseline and after four months

Method of measurement

Blood cholesterol level was determined in laboratory by commercially available kit

4

Description

Triglyceride

Timepoint

At baseline and after four months

Method of measurement

Blood triglyceride level was determined in laboratory by commercially available kit

5

Description

AST (aspartate aminotransferase)

Timepoint

At baseline and after four months

Method of measurement

Blood AST level was determined in laboratory by commercially available kit

6**Description**

ALT (alanine aminotransferase)

Timepoint

At baseline and after four months

Method of measurement

Blood ALT level was determined in laboratory by commercially available kit

7**Description**

Creatinine

Timepoint

At baseline and after four months

Method of measurement

Blood creatinine level was determined in laboratory by commercially available kit

Intervention groups**1****Description**

Citrullus colocynthis capsule 100mg/TDS for 4 months

Category

Treatment - Drugs

2**Description**

Placebo capsule 100mg/TDS for 4 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Asghar diabetic clinic

Full name of responsible person

Maryam Yaghoobi

Street address

Ali Asghar clinic, Azadi street

City

Zahedan

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Mahmodzadeh Saqeb Hamid Reza

Street address

Zahedan University of Medical Sciences, Daneshgah Ave. Dr. Hesabi square

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Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

2**Sponsor****Name of organization / entity**

Vice chancellery for research, Institute of medicinal plants

Full name of responsible person

Reza Hajiaghaee

Street address

Jahad daneshgahi research society, Kavosh blvd, Tehran-Qazvin highway, Karaj, Iran.

City

Karaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellery for research, Institute of medicinal plants

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Yaghoobi

Position

M.Sc.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty