Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 915 341 3296

Email address

yaghoobi@zaums.ac.ir

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 capsule100mg/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
City
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
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Yaghoobi
Position
M.Sc.
Other areas of specialty/work
Street address
Dr. Hesabi square, Daneshgah Ave.
City
Zahedan
Postal code
16743463
Phone
+98 54 1244 2482
Fax
+98 915 244 2481
Email
yaghoobi@zaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Institute of Medicinal Plants
Full name of responsible person
Hasan Fallah Huseini
Position
Ph.D.
Other areas of specialty/work
Street address
Research Complex of Jahad Daneshgahi, ACECR, Kavosh Boulevard, Supa Boulevard, Karaj-Qazvin Highway
City
Karaj
Postal code
13601360
Phone
+98 26 3476 4010
Fax
+98 26 3476 4021
Email
huseini_fallh@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Yaghoobi
Position
M.Sc.
Other areas of specialty/work
Street address
Nursing and midwifery collegue
City
Zahedan
Postal code
16743463
Phone
+98 54 1244 2482
Fax
+98 54 1244 2481
Email
yaghoobi@zaums.ac.ir
Web page address

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