

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 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

###### 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 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

#### 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****Fax**

+98 26 3476 4021

**Email**

huseini\_falh@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**

## 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 Jihad Daneshgahi, ACECR,  
Kavosh Boulevard, Supa Boulevard, Karaj-Qazvin  
Highway

**City**

Karaj

**Postal code**

13601360

**Phone**

+98 26 3476 4010

## 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*