

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Citrullus Colocynthis Schrad comparison with Plasebo on dyslipidemia in 2 type diabetic patients: Clinical trial double blind

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of this plant on blood lipoproteins on type 2 diabetic patients.

##### Design

This study is a phase 2 clinical trial, a randomized double-blind and random sequences generated based on a sample of randomly placed in two groups and the placebo group. Related information is obtained through interviews and laboratory measurements. The subjects were selected from patients with type 2 diabetes to number 70 in the diabetes clinic in Sabzevar, Iran.

##### Settings and conduct

The target population included all patients who have type 2 adult onset diabetes health records at the clinic Sabzevar University of Medical Sciences. Samples were randomly assigned into two groups of intervention and placebo groups. To duplicate this research, cans containing Handal or placebo capsules is coded by an individual other than the researcher. At the start of the study, all patients receive 5 ml of blood intravenously in fasting state. The samples are asked to make no changes in their diet and physical activity during the study period and to inform any researchers about any changes in their medicines. Drug use will continue until the end of the 8th week. At the end of the 8th week, blood samples are taken and the study variables are reviewed. The results are compared at week 8 with the starting values of the study and the percentage of changes is calculated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were: having uncontrolled blood lipids (LDL level greater than 100 mg/dl) at least 4 months before the beginning of study and receiving Statins as well as low fat diet; being younger than 65 and older than 40 years old; having dossier in the diabetes clinic; The patient's willingness to participate in the research and being diabetic Type 2 for at least 1 year. exclusion criteria were: Having cardiovascular diseases, respiratory disease, gastrointestinal diseases, liver, kidney or any

infectious diseases; being pregnant or breastfeeding and having previous history of paroxysm or surgery on the digestive system, unwillingness to continue cooperation, sick travel or death, create unwanted side effects, do not take medicine for more than a week, the occurrence of a stressful event in life and body mass index (BMI) lower than 18.5 and higher than 25.

##### Intervention groups

In the intervention group, the specimens for 8 weeks Handal capsules (125 mg) once a day (before lunch) receive. In the same manner the placebo group received placebo capsules containing starch and tragacanth (125 mg) to receive. Preparation of this capsule is carried out at the Faculty of Pharmacy of Traditional Medicine, University of Tehran. Plants used in this compound are used after the approval of the relevant specialists and receive the Herbarium number.

##### Main outcome variables

The main outcome of this study, the percentage change in serum LDL; triglycerides; total cholesterol and serum HDL from beginning of study to end it.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140505017585N3**

Registration date: **2018-02-13, 1396/11/24**

Registration timing: **retrospective**

Last update: **2018-02-13, 1396/11/24**

Update count: **0**

##### Registration date

2018-02-13, 1396/11/24

##### Registrant information

##### Name

Bitá Barghamadi

##### Name of organization / entity

Sabzevar university of medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 4464 5620

**Email address**

barghamadib1@medsab.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Dr Mohamadzadeh Mohamad. Research Deputy Sabzevar University of Medical Sciences

**Expected recruitment start date**

2017-01-04, 1395/10/15

**Expected recruitment end date**

2017-07-06, 1396/04/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Citrullus Colocynthis Schrad comparison with Plasebo on dyslipidemia in 2 type diabetic patients: Clinical trial double blind

**Public title**

Effect of Citrullus Colocynthis Schrad in diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Inclusion criteria were: being diabetic Type 2 for at least 1 year; Having uncontrolled blood lipids (LDL level greater than 100 mg/dl) at least 4 months before the beginning of study and receiving Statins as well as low fat diet; Being younger than 65 and older than 40 years old; Having dossier in the diabetes clinic; The patient's willingness to participate in the research;

**Exclusion criteria:**

Exclusion criteria were: Having Chronic physical disorders like cardiovascular diseases, respiratory, liver, and or ,, , , the and body mass index Having previous history of paroxysm; Surgery on the digestive and Kidney system; BMI lower than 18.5 and higher than 25; Unwillingness to continue cooperation; Death or sick travel; Being pregnant or breastfeeding; Create unwanted drug side effects; Do not take medicine for more than a week; Occurrence of a stressful event in life;

**Age**

From **40 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are selected by available sampling method, and after completing the written consent form, they enter the study . Then, for each questionnaire, adjusted according to the demographic and clinical characteristics, it is completed by a evaluator. Samples were randomly assigned to either the intervention or placebo groups based on randomized sequencing. A random sequence will be generated by random four-way blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To duplicate this research, cans containing Handal or placebo capsules is coded by an individual other than the researcher so that the researcher is not aware of the type of supplement received by each group.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Sabzevar university of Medical Sciences

**Street address**

Ethics committee, Pardis building, Tohid shahr Boulevard, Sabzevar Town

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617684155

**Approval date**

2015-10-12, 1394/07/20

**Ethics committee reference number**

IR.MEDSAB.REC.1394.83

**Health conditions studied**

**1**

**Description of health condition studied**

Diabete

**ICD-10 code**

E10,E11,E1

## ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

Cholesterol

#### Timepoint

Blood test in beginning of study and Three months after the intervention began

#### Method of measurement

Blood test

### 2

#### Description

Triglyceride

#### Timepoint

Blood test in beginning of study and Three months after the intervention began

#### Method of measurement

Blood test

### 3

#### Description

LDL

#### Timepoint

Blood test in beginning of study and Three months after the intervention began

#### Method of measurement

Blood test

### 4

#### Description

HDL

#### Timepoint

Blood test in beginning of study and Three months after the intervention began

#### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Handal Capsule 125 mg orally, With combinations of restitute (Tragacanth, Starch, Arabic Gum, Fennel All Equal 25 mg); Once a day before of lunch; for 2 months. Preparation of this capsule is carried out at the Faculty of Pharmacy of Traditional Medicine University of Tehran.

#### Category

Treatment - Drugs

### 2

#### Description

Placebo capsule 125 mg orally, includes Tragacanth and Starch in equal amounts, once a day before of lunch; for 2 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabete clinice

##### Full name of responsible person

Dr Shahrabadi Hosein

##### Street address

Oxygen building, Enghelab Avenue, Sabzevar Town

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617684155

##### Phone

+98 51 4401 1569

##### Email

Shahrabadih@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Dr Mohamadzade Mohamad

##### Street address

Deputy of Research Department, University of Medical Sciences Pardis, Above the cemetery o Anonymo us Martyrs,Tohid shahr Boulevard, City of Sabzevar

##### City

Sabzevar

##### Province

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##### Postal code

9617684155

##### Phone

+98 51 4401 1569

##### Email

Drshurideh@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sabzevar 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

**Province**

Razavi Khorasan

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9613873136

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fereshtehghorat@gmail.com

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Barghamadi Bita

**Position**

Research expert

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Deputy of Health Department of University of Medical Sciences, Taleghani corner 27, Taleghani St., City of Sabzevar,

**City**

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**Full name of responsible person**

Barghamadi Bita

**Position**

Research expert

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Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Health center, Taleghani street, Sabzevar city

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Dr Ghorat Fereshteh

**Position**

Ph.D in traditional medicine

**Latest degree**

Ph.D.

**Other areas of specialty/work****Street address**

Traditional and complementary medicine research center, Pardis Building, Above the cemetery of Anonymous Martyrs, Tohid shahr Boulevard, Sabzevar

**City**

Sabzevar

**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**

No more information

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable