Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Bita Barghamadi

Name of organization / entity

Sabzevar university of medical sciences

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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

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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 begining of study and Three months after the intervention began

Method of measurement

Blood test

2

Description

Triglyceride

Timepoint

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

Method of measurement

Blood test

3

Description

LDL

Timepoint

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

Method of measurement

Blood test

4

Description

HDL

Timepoint

Blood test in begining 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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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

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

Person responsible for general inquiries

Contact
Name of organization / entity
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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