

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of a Polyherbal compound on the level of blood lipids in diabetic patients

Protocol summary

Summary

In this clinical trial 50 patients with type-2 diabetes will be enrolled in two groups containing 25 subjects. In group 1, patients will receive only oral hypoglycemic drugs (metformin and/or glibenclamide) and statins agents for control of blood glucose and lipids. In group 2, patients will receive the polyherbal compound in addition to those current drugs. Before treatment, the level of total cholesterol, LDL, VLDL, HDL, triglyceride, fasting blood Sugar, HbA1c, hepatic enzyme, BUN and creatinine will be determined in venous blood samples of patients. Then, the polyherbal compound will be administered twice daily (dinner and lunch). The patient will keep the usual diabetic diet and the standard hypoglycemic medications during study. After 1, 2 and 3 months the patients will be visited by physician to check vital signs, blood sugar and any possible side effects. After 1 and 3 months, the level of blood glucose, lipids, hepatic enzyme, BUN and creatinine will be determined again. All parameters will be measured using standard kits and autoanalyzer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030116776N1**

Registration date: **2014-04-23, 1393/02/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-23, 1393/02/03

Registrant information

Name

Ahmad Ghorbani

Name of organization / entity

Mashhad University of Medical Sciences

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+98 51 1800 2262

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2015-03-11, 1393/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a Polyherbal compound on the level of blood lipids in diabetic patients

Public title

Effects of a Polyherbal compound on the level of blood lipids in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

1. Age: > 25 2. Non-insulin dependent diabetic patients 3. Fasting blood Sugar > 140 mg/dl and HbA1c > 7% 4. Serum Cholesterol > 200 mg/dl and Triglyceride > 150 mg/dl 5. Patients with chronic renal, hepatic or infectious diseases will be excluded. 6. Patients with history of any allergy to Garlic, Black seed, Aloe vera, fenugreek, Psyllium and Silybum marianum will be excluded. 7. No addiction to cigarette, alcohol or any other drugs.

Age

From **25 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Daneshgah St.

City

Mashhad

Postal code**Approval date**

2013-10-19, 1392/07/27

Ethics committee reference number

911068

Health conditions studied**1****Description of health condition studied**

Diabetic Dyslipidemia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Cholestrol and triglyceride

Timepoint

At the begining of study as well as after1 and 3 months

Method of measurement

Standard Kits

Secondary outcomes

empty

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

Patients in this group will receive atorvastatin (20 mg, once a day) drug plus placebo for decrease of serum lipids for 3 months.

Category

Placebo

2**Description**

Patients in this group will receive atrovastatin drug plus polyherbal compound. The compound is prepared as sachet (8.7g) containing powder of Allium sativum, Nigella sativa, Trigonella foenum, Psyllium, silybum marinum and Aloe vera. The compound will administrate twice daily for 3 months.

Category

Treatment - Drugs

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

Clinic of Emam Reza Hospital

Full name of responsible person**Street address****City**

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Council of Mashhad University of Medical Sciences, Mashhad, IRAN

Full name of responsible person

Mohammad Ramezani

Street address

Ghoraishi Building, University st.

City

Mashhad

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

Yes

Title of funding source

Research Council of Mashhad University of Medical Sciences, Mashhad, IRAN
Proportion provided by this source
100
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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Person responsible for updating data

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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