Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Role of silymarine (livergol) in improving control indices of diabetes type II

Protocol summary

Study aim
The present study was conducted to assess the effect of addition of a herbal drug; silymarine (livergol) to treatment regimen of diabetic patients with aim of better control of the disease.

Design
In the present study, patients with diabetes type II who attend in OPD clinic of Buali hospital, Qazvin, Iran will be included. They will be randomly divided into two groups and treated for 4 months. The first group will receive silymarine (livergol 70) 140 mg PO Bid. The second group will receive placebo with the same order.

Settings and conduct
The current study will be performed in OPD specialty clinic of Buali hospital, Qazvin, Iran. The participants will be sent to a predetermined pharmacy to receive their drugs randomly without knowing of its content.

Participants/Inclusion and exclusion criteria
Patients with diagnosis of diabetes type II, if provided informed consent for participation in the study and met inclusion criteria

Intervention groups
The control group: will receive basic medical management included instructions for proper diet and avoiding sedentary lifestyle, administration of insulin and oral hypoglycemic if clinically indicated+ placebo. The study group: will receive basic medical management included instructions for proper diet and avoiding sedentary lifestyle, administration of insulin and oral hypoglycemic if clinically indicated+ silymarine.

Main outcome variables
FBS; HbA1C; lipid profile; BMI;

General information

Reason for update

Acronym
DM

IRCT registration information
IRCT registration number: **IRCT20150204020951N4**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **prospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date
2018-01-21, 1396/11/01

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Role of silymarine (livergol) in improving control indices of diabetes type II

Public title

Silymarine in control of diabetes type II

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

suffering from diabetes mellitus according to WHO criteria at least 1 year duration of the disease

Exclusion criteria:

Presence of acute complications of DM (such as DKA) presence of vascular complications of DM presence of diabetic foot Other major renal, hepatic, and heart diseases

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, patients who participate in the study will be blinded through administration of placebo. The researcher who will assess the out comes after complete of the study will be also blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Research Deputy; Faculty of Medicine; Qazvin University of Medical Sciences; Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2017-07-26, 1396/05/04

Ethics committee reference number

IR.QUMS.REC. 1396.204

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Before the study; two and four months later

Method of measurement

As reported by laboratory

2

Description

Lipid profile

Timepoint

Before the study; two and four months later

Method of measurement

As reported by laboratory

3

Description

HbA1c

Timepoint

Before the study; four months later

Method of measurement

As reported by laboratory

4

Description

Body Mass Index

Timepoint

Before the study; four months later

Method of measurement

By one of the researchers after measuring body weight and height

Secondary outcomes

empty

Intervention groups

1

Description
The control group: will receive basic medical management included instructions for proper diet and avoiding sedentary lifestyle, administration of insulin and oral hypoglycemic if clinically indicated+ placebo. The study group: will receive basic medical management included instructions for proper diet and avoiding sedentary lifestyle, administration of insulin and oral hypoglycemic if clinically indicated+ silymarine.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
OPD clinic of internal medicine, Buali hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Qazvin 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
Qazvin University of Medical Sciences

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Position
Assistant professor

Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after removing the personal identifications.
When the data will become available and for how long
For six months after publication of results of the study
To whom data/document is available
Academic researchers in the field of medicine
Under which criteria data/document could be used
For design of the future related study or meta-analysis
From where data/document is obtainable
Via email of the corresponding author of the related article
What processes are involved for a request to access data/document
Within 30 days after the request and validation of the requesting person
Comments