

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the effects of Cornus Mas L. fruit extract capsule on blood glucose and HgbA1C in patients with type 2 diabetes mellitus

Protocol summary

Summary

This clinical trial study aimed to evaluate the cornus mas effect on blood glucose and HgbA1C levels in patients with type 2 diabetes mellitus. Inclusion criteria: Type 2 diabetes mellitus patients (according to America Diabetes Association ADA), glycosylated hemoglobin levels above 7% and less than 12%. and Exclusion criteria: Individuals with a history of diseases; liver and kidney; with the medication use affecting blood sugar levels; pregnant and breastfeeding. It was conducted among 60 patients with type 2 diabetes mellitus, aged 18-80 years. Participants were randomly assigned into two groups. Participants of the case group were asked to consume 4 of capsule dosage form cornus mas twice a day after the lunch and dinner. At baseline and after the 6th wk of the trial, fasting blood samples were collected from both groups to measure blood glucose and HgbA1C levels and other factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305059662N6**

Registration date: **2013-06-12, 1392/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Sedigheh Asgary

Name of organization / entity

Isfahan Cardiovascular Research Center ,Isfahan
Cardiovascular Research institute , Physiology Re

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9090

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-12-22, 1391/10/02

Expected recruitment end date

2013-06-09, 1392/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Cornus Mas L. fruit extract capsule on blood glucose and HgbA1C in patients with type 2 diabetes mellitus

Public title

Effect of Cornus Mas L. fruit extract on patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetes mellitus patients (according to America Diabetes Association ADA); glycosylated hemoglobin levels above 7% and less than 12%; subjects between the ages 18 to 80 years; No alcohol and other drug abuse; Does not change the dose of anti-diabetic medication within 1 month Exclusion criteria: Individuals with a history of diseases; liver and kidney; with the medication use affecting blood sugar

levels; pregnant and breastfeeding; hypersensitivity to the drug used in this study; the incidence of diabetic foot ulcers; heart disease, severe systolic blood pressure ≥ 180 and / or pressure diastolic ≥ 110

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

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

Isfahan University of Medical Sciences

Street address

Hezar jirib St. Isfahan Isfahan Iran, Islamic Republic Of

City

Isfahan

Postal code

Approval date

2012-11-12, 1391/08/22

Ethics committee reference number

2964/9/3

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

FBS level

Timepoint

Baseline and after 6 weeks

Method of measurement

By autoanalyzer

2

Description

Hgb A1C level

Timepoint

Baseline and after 6 weeks

Method of measurement

By autoanalyzer

Secondary outcomes

1

Description

Serum creatinine

Timepoint

Before and after 6 weeks

Method of measurement

By autoanalyzer

2

Description

Alanine transaminase (ALT)

Timepoint

Before and after 6 weeks

Method of measurement

By autoanalyzer

3

Description

Aspartate transaminase (AST)

Timepoint

Before and after 6 weeks

Method of measurement

By autoanalyzer

4

Description

length

Timepoint

Before and after 6 weeks

Method of measurement

meter

5

Description

Weight

Timepoint

Before and after 6 weeks

Method of measurement

Scale

Intervention groups

1

Description

case group:no treatment

Category

Placebo

2

Description

Participants of the case group were asked to consume 4 of cornus mas twice a day after the lunch and dinner

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center

Full name of responsible person

Mahtab Keshvari

Street address

Khorram Street, Jomhori Square

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Gholam Hossin Sadri

Street address

Hezar jirib St.

City

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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

Isfahan University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Cardiovascular Research Center, Applied Physiology Research Center, Isfahan University of Me

Full name of responsible person

Dr. Siavash

Position

Pharmacist and PhD Pharmacogenetics

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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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