Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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/د

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
Isfahan
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
Street address
Khorram Street, Jomhoori Square
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Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
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Web page address

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