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
Email address
s_asgari@crc.mui.ac.ir

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 $\geq 180$ and / or pressure diastolic $\geq 110$

**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/

**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**
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
Hazar 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 Med
Full name of responsible person
Dr. Siavash
Position
Pharmacist and PhD Pharmacogenetics
Other areas of specialty/work
Street address
Khorram Street, Jomhori Square
City
Isfahan
Postal code
+98 31133595959
Fax
Email
sasgary@yahoo.com
Web page address

Person responsible for updating data
Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Abdollah Gorji
Position
md Pharmacist
Other areas of specialty/work
Street address
Hazar jirib st.
City
Isfahan
Postal code
+98 31 1668 8138
Fax
Email
mahtabkeshvari87@yahoo.com
Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty