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%. 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

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**
By autoanalyzer

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**
  - 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

**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, Jomhori Square
- **City**
  - Isfahan
- **Postal code**
- **Phone**
  - +98 3113359595
- **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**
  - Hezar jirib st.
- **City**
  - Isfahan
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- **Phone**
  - +98 31 1668 8138
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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**
- empty

**Study Protocol**
- empty

**Statistical Analysis Plan**
- empty