Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Effect of Cornus mas L. on Inflammatory Risk Factors, Lipid Profile and Apolipoproteins in Dyslipidemic Children

Protocol summary

Summary

This clinical trial study aimed to evaluate the cornus mas effect on inflammatory risk factors, lipid profile and apolipoproteins in dyslipidemic children. It was conducted among 40 dyslipidemic children, aged 9-16 years. Participants were randomly assigned into two groups. Participants of the case group were asked to consume 50 gram of cornus mas twice a day after the lunch and dinner. At baseline and after the 3rd and 6th wk of the trial, fasting blood samples were collected from both groups to measure total cholesterol, high and low-density lipoprotein, triglyceride and other factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206109662N3**
Registration date: **2012-09-16, 1391/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Sedigheh Asgary

Name of organization / entity

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

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2011-08-29, 1390/06/07

Expected recruitment end date

2011-10-11, 1390/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Cornus mas L. on Inflammatory Risk Factors, Lipid Profile and Apolipoproteins in Dyslipidemic Children

Public title

Effect of Cornus mas L. on Cardiovascular disease in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: subjects that had at least one of the dyslipidemic measures such as TG (≥150 mg/dL), TC (≥170 mg/dL), LDL (≥130 mg/dL) and low HDL (<35 mg/dL) in serum; dyslipidemic children between the ages of 9-16 years. Exclusion criteria: known diabetes mellitus; liver disease; nephrotic syndrome; thyroid disorders; chronic pancreatitis; bile duct disorders; the use of medication that would alter lipid metabolism; the informed consent not being signed.

Age

From **9 years** old to **16 years** old

Gender

Both

Phase

1

Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan Cardiovascular Research Center
Street address
Sedigh-e-Tahere Research Center, Khoram St., Jomhouri Sq., Isfahan, Iran
City
Isfahan
Postal code
Approval date
2010-07-23, 1389/05/01
Ethics committee reference number
89108

Health conditions studied

1

Description of health condition studied
dyslipidemia
ICD-10 code
E78.1
ICD-10 code description
Endogenous hyperglyceridaemia Fredrickson's hyperlipoproteinaemia, type IV Hyperlipidaemia, group B Hyperprebetalipoproteinaemia Very-low-density-lipoprotein-type [VLDL] hyperlipoproteinaemia

Primary outcomes

1

Description
total cholesterol
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
spectrophotometeric method

2

Description
low-density lipoprotein
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
Friedewald formula

3

Description
high-density lipoprotein
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
spectrophotometeric method

4

Description
triglyceride
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
spectrophotometeric method

Secondary outcomes

1

Description
WHR
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
tape

2

Description
BMI
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
tape

3

Description
VCAM
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
ELISA kit

4

Description
ICAM
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement

ELISA kit

5

Description
CRP
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
automated chemistry analyzer

6

Description
apo A
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
automated chemistry analyzer

7

Description
apo B
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
automated chemistry analyzer

8

Description
HDL/LDL
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
spectrophotometeric method

9

Description
HDL/TC
Timepoint
baseline and after the 3 and 6 wk of the treatment
Method of measurement
spectrophotometeric method

Intervention groups

1

Description
case group: using 50 g of CM twice a day after the lunch and dinner
Category
Prevention

2

Description
case group:no treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Cardiovascular Research Center
Full name of responsible person
Mitra Najafi
Street address
Isfahan Cardiovascular Research Center, Khorram Ave. Isfahan. I.R. Iran.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Mahmuod Rafieian-Kopaei
Street address
Shahrekord University of Medical Sciences
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord 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
Sedigh-e-Tahere Research Center
Full name of responsible person
Sedigh Asgary
Position
Professor of Pharmacognosy

Other areas of specialty/work
Street address
Sedigh-e-Tahere Research Center, Khoram St., Jomhouri Sq., Isfahan, Iran
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Person responsible for updating data

Contact
Name of organization / entity
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Somayeh Najafi
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MSc/researcher
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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