Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical evaluation of Portulaca oleraceae seed in comparision with placebo on treatment of dyslipidemia in adolescents between 12-18 years old

Protocol summary

Summary

Study: Adolescent between 12 to 18 years old with dyslipidemic features randomly divided into groups of control and case. Each group has 37 members. Control group get placebo and case group get Portulaca oleraceae seed powder. Portulaca oleraceae seed powder in 500mg capsules was used thrice a day by patients for one month. Each patient was bled two times; first at the beginning before entrancing study and second at the end of study. One month after consumption of drug and placebo by case and control group respectively, laboratory parameters like TG, TC, LDL and HDL was measured by autoanalyzer method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109122306N4**
Registration date: **2012-07-26, 1391/05/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-26, 1391/05/05

Registrant information

Name

Ali Mohammad Sabzghabaee

Name of organization / entity

Isfahan university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7070

Email address

sabzghaba@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-05-05, 1390/02/15

Expected recruitment end date

2011-12-06, 1390/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of Portulaca oleraceae seed in comparision with placebo on treatment of dyslipidemia in adolescents between 12-18 years old

Public title

Preliminary clinical evaluation of Portulaca oleraceae seed on treatment of dyslipidemia in adolescents

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1)adolescents between 12 to 18 years old that have at least one of these criteria: a: triglyceride more than 90 percentile b: total cholesterol more than 90 percentile c: LDL more than 90 percentile d:HDL less than 10 percentile 2) Not using tobacco 3) No history of alcohol consumption or drug abuse 4) No history of metabolic diseases like diabetes, thyroid gland dysfunction, nephrotic syndrome, chronic pancreatitis, liver and gall bladder diseases that affects lipid profiles 5) No use of drugs which affect lipid profiles like statins and hormonal pills like estrogens, progestrones and oral

contraceptives. Exclusion criteria: 1) Lack of patient's compliance with drug regimens at least for one week. 2) Pregnancy and lactation 3) Drug sensitivity 4) Suffering from any diseases which interact with lipid profiles 5) Intake of any kind of drugs or other compounds lowering lipid profile like corticosteroids, androgens, estrogenes, progestines, thiazides, beta blockers and thyroid hormones

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 ethics Committee

Street address
Vice chancellery for research, Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2010-03-01, 1388/12/10

Ethics committee reference number
388592

Health conditions studied

1

Description of health condition studied
Dyslipidemia

ICD-10 code
E78.5

ICD-10 code description
Hyperlipidaemia,unspecified

Primary outcomes

1

Description
HDL cholestrol

Timepoint
Before intervention, one month after intervention

Method of measurement
mg/dl through using laboratory kit

2

Description
LDL cholestrol

Timepoint
Before intervention, one month after intervention

Method of measurement
mg/dl through using laboratory kit

3

Description
Triglyceride

Timepoint
Before intervention, one month after intervention

Method of measurement
mg/dl through using laboratory kit

4

Description
Total cholestrol

Timepoint
Before intervention, one month after intervention

Method of measurement
mg/dl through using laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Portulaca oleraceae seed powder in 500 mg capsules thrice a day for one month

Category
Treatment - Drugs

2

Description
placebo powder in 500mg capsules thrice a day for one month

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sedighe Tahere, Isfahan Cardiovascular Research Center
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Peyman Adibi
Street address
Isfahan University of Medical Sciences, Daneshgah st. beginning, Azadi sq.Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellery for research, 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
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Hadi jelokhanian
Position
Student of pharmacy
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Daneshgah st. beginning, Azadi sq.Isfahan
City
Isfahan
Postal code
Phone
+98 31 1336 8589
Fax
Email
hadi_jelokhanian@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Hadi Jelokhanian
Position
Student of pharmacy
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Daneshgah st. beginning, Azadi sq., Isfahan
City
Isfahan
Postal code
Phone
+98 31 1336 8589
Fax
Email
hadi_jelokhanian@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Hadi Jelokhanian
Position
Student of pharmacy
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences, Daneshgah st. beginning, Azadi sq.Isfahan
City
Isfahan
Postal code
Phone
+98 31 1336 8589
Fax
Email
hadi_jelokhanian@yahoo.com
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