

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

sabzghaba@pharm.mui.ac.ir

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.

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

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

Scientific title

Clinical evaluation of *Portulaca oleraceae* seed in comparison 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, progesterones 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, estrogens, 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**

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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