Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Clinical evaluation of Rhus coriaria fruit 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 Rhus coriaria powder. Rhus coriaria powder in 500mg gr capsule 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: **IRCT201109122306N3**
Registration date: **2012-01-01, 1390/10/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-01, 1390/10/11

Registrant information

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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 Rhus coriaria fruit in comparision with placebo on treatment of dyslipidemia in adolescents between 12-18 years old

Public title

Preliminary clinical evaluation of Rhus coriaria fruit 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
2011-02-08, 1389/11/19
Ethics committee reference number
388595

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
Rhus coriaria fruit powder in 500 mg caspsules thrice a day after meal for one month
Category
Treatment - Drugs

2

Description
placebo in 500 mg capsules thrice a day after meal 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

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Student of pharmacy

Other areas of specialty/work

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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