

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Clinical evaluation of Hibiscus sabdariffa L. in comparison 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 36 members. Control group get placebo and case group get Hibiscus sabdariffa powder. Hibiscus sabdariffa calyx powder in 2 gr sachets was used three times 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 auto analyzer method

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109122306N2**
Registration date: **2011-12-28, 1390/10/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-28, 1390/10/07

Registrant information

Name

Ali Mohammad Sabzghabae

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 Hibiscus sabdariffa L. in comparison with placebo on treatment of dyslipidemia in adolescents between 12-18 years old

Public title

Preliminary clinical evaluation of Hibiscus sabdariffa L.calyx 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) Not using 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: **72**

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.

Street address

Vice chancellor for research, Isfahan University of
Medical Sciences, Isfahan

City

Isfahan

Postal code

Approval date

2010-01-02, 1388/10/12

Ethics committee reference number

388590

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

LDL Cholestrol

Timepoint

Before intervention, one month after intervention

Method of measurement

mg/dl through using laboratory kit

2

Description

HDL 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

Hibiscus sabdariffa L. calices powdered and packed in 2
gr sachets. Each patient consumed 3 sachets per day
during one month.

Category

Treatment - Drugs

2

Description

Placebo powder packed in 2 gr sachets and each patient
consumed 3 sachets per day during 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 chancellor 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 chancellor 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

Ehsan Ataei

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 1778 2798

Fax

Email

ataei_ehsan109@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

Ehsan Ataei

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 1778 2798

Fax

Email

ataei_ehsan109@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

Ehsan Ataei

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 1778 2798

Fax

Email

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