# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 2026

## Clinical evaluation of Hibiscus sabdariffa L. 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 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 Sabzghabaee
**Name of organization / entity**
Isfahan university of Medical Sciences
**Country**
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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 Hibiscus sabdariffa L. in comparision 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, 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: **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**
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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*