

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effects of jujube fruits on lipid profile in hyperlipidemic patients

Protocol summary

Summary

In this double-blind, placebo, Randomized controlled clinical trial study in hyperlipidemic patients 90 volunteers, subjects aged 35-70 years and over 5/18 mM cholesterol (200 mg per deciliter), and over 3/ 37mM LDL (130 mg dL) will be selected. The purpose of this study, is to investigate the effect of jujube fruits (Ziziphus vulgaris L.) extract capsule On, Inflammatory factor (hs-CRP) levels, the lipid profile, Apolipoprotein A B and blood sugar levels in hyperlipidemic patients. Individuals with a history of diseases; diabetes; cardiovascular disease; liver and kidney as well as pregnant and breastfeeding; supplements like fish oil which is affect on blood lipids levels; the use of immunosuppressive drugs will be excluded. Inflammatory factor (hs-CRP) levels, the lipid profile, Apolipoprotein A B and blood sugar levels will be measured using ELISA kits. Participants will be randomly divided into three groups. Group1 will consume 2 jujube fruits extract capsule(500mg). Group2 will consume 2 placebo capsule and Group3 will take A tablet to atorvastatin(20mg) 4 weeks. Then at the beginning and end of each 4-week period aforementioned factors will be measured again for each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308319662N7**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-23, 1392/07/01

Registrant information

Name

Sedigheh Asgary

Name of organization / entity

Isfahan Cardiovascular Research Center ,Isfahan
Cardiovascular Research institute , Physiology Re

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9090

Email address

s_asgari@crc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

1- Isfahan University of Medical Sciences 2 - Razi Herbal
Research Center, Lorestan University of Medical Sciences

Expected recruitment start date

2013-11-21, 1392/08/30

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of jujube fruits on lipid profile in hyperlipidemic
patients

Public title

Effects of jujube fruits on lipid profile in hyperlipidemic
patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : in hyperlipidemic patients; subjects
aged 35-70 years ; over 5/18 mM cholesterol (200 mg
per deciliter); over 3/ 37mM LDL (130 mg dL). exclusion
criteria : Individuals with a history of diseases; diabetes;
cardiovascular disease; liver and kidney as well as
pregnant and breastfeeding; supplements like fish oil

which is affect on blood lipids levels; the use of immunosuppressive drugs

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Razi Herbal Medicines Research Center, Lorestan

Street address

St.shafa (Razi), Vice Chancellor for Research and Technology - Razi Herbal Medicines Research Center

City

Khorramabad

Postal code

Approval date

2013-06-09, 1392/03/19

Ethics committee reference number

92/5

Health conditions studied

1

Description of health condition studied

Other disorders of lipoprotein metabolism

ICD-10 code

E78.8

ICD-10 code description

Other disorders of lipoprotein metabolism

2

Description of health condition studied

Pure hypercholesterolaemia

ICD-10 code

E78.0

ICD-10 code description

Pure hypercholesterolaemia

3

Description of health condition studied

Hyperlipidaemia, unspecified

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

total cholestrol

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

2

Description

HDL

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

3

Description

LDL

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

4

Description

TG

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

Secondary outcomes

1

Description

hs-CRP

Timepoint

Before and after 4 weeks

Method of measurement

ELISA Kit

2

Description

apo A

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

3

Description

apo 8

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

4

Description

FBS

Timepoint

Before and after 4 weeks

Method of measurement

Parss Azmon KIT/Device Hitachi

Intervention groups

1

Description

control group: take placebo capsol twice a day after the lunch and dinner for a month

Category

Placebo

2

Description

case group: take Zizophorus vulgaris capsol twice a day after the lunch and dinner for a month

Category

Treatment - Drugs

3

Description

case group: taking one Atorvastatin Tablet a day after the lunch and dinner

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Center Sedigheh Tahereh

Full name of responsible person

Mahtab Keshvari

Street address

Khorram Street, Jomhori Square

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

RAZI Research Center Lorestan University of Medical Sciences

Full name of responsible person

Dr. Bahram Rasoulia

Street address

Shafa St. (Razi) - Vice Chancellor for Research and Technology

City

khoramabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

RAZI Research Center Lorestan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Gholam Hossain Sadri

Street address

Hezar Jirib St.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Cardiovascular Research Center, Applied
Physiology Research Center, Isfahan University of Me

Full name of responsible person

Sedigheh Asgary

Position

Pharmacist and PhD Pharmacogenetics

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan Cardiovascular Research Center

Full name of responsible person

Mahtab keshvari

Position

MSc / BSc Research

Other areas of specialty/work

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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