

# 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**

**Street address**

Cardiovascular Research Center, Khorram Street,  
Jomhoori Square

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1335 9090

**Fax**

**Email**

sasgary@yahoo.com

**Web page address**

## 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**

**Street address**

Cardiovascular Research Center, Khorram Street,  
Jomhoori Square

**City**

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**Postal code**

**Phone**

+98 31 1335 9090

**Fax**

**Email**

mahtabkeshvari87@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*