

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The investigation of the effects of Capparis Spinosa pickle on lipid profile in hypercholesterolemia.

Protocol summary

Summary

This study aims to investigate the effect of the Capparis Spinosa pickle on Lipid Profile, Liver Enzymes, Fasting Blood Glucose, BUN & Cr among Hypercholesterolemia patients. The total sample was 60 people, which included the two intervention and control groups (30 people each). Using the Rend I & II software, the samples were randomly divided into the two intervention and control groups. The study was not blinded. Inclusion criteria: Hyperlipidemia (LDL $\geq$ 100 based on Framingham criteria); sex: male, age 40 to 60 years. Exclusion criteria: Hyperlipidemia during treatment; pregnancy and lactation; CHD patient; BP $\geq$ 140/90; Coagulopathies; thyroid disease; Having a particular diet, or the consumption of medicine that affects blood lipid level (e.g. OCP, corticosteroid, etc.), special illnesses that affect lipid profile (e.g. renal failure), discontinuing treatment at any stage, smoking, drug and alcohol abuse, taking medicine or doing anything that affects lipid profile 30 days prior to the study, any side effect that might stop treatment, major stress levels based on DSM IV during the study or the last three months. Variables are lipid profile, liver enzymes, FBS, BUN, Cr & appetite Interventions included: Standard Treatment (a training course in lifestyle & 10 mg Atorvastatin tablets) to both groups, daily consumption of 40 grams of Capparis Spinosa pickle (only offered to the intervention group) for 8 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032827532N1**

Registration date: **2017-03-28, 1396/01/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-28, 1396/01/08

Registrant information

Name

Saeed Sardari

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 51210

Email address

s.sardari@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2017-07-30, 1396/05/08

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of the effects of Capparis Spinosa pickle on lipid profile in hypercholesterolemia.

Public title

Effects of Capparis pickle on blood lipid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hyperlipidemia (LDL $\geq$ 100 based on

Framingham criteria), sex: male, age 40 to 60 years.
Exclusion criteria: Hyperlipidemia during treatment; pregnancy and lactation; CHD patient; BP $\geq$ 140/90; Coagulopathies; thyroid disease; Having a particular diet, or the consumption of medicine that affects blood lipid level (e.g. OCP, corticosteroid, etc.); special illnesses that affect lipid profile (e.g. renal failure); discontinuing treatment at any stage; smoking, drug and alcohol abuse; taking medicine or doing anything that affects lipid profile 30 days prior to the study; any side effect that might stop treatment and major stress levels based on DSM IV during the study or the last three months.

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University

Street address

Shahed University, in front of the shrine Imam
Khomeini (RA), Persian Gulf Highway

City

Tehran

Postal code

3319118651

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR,Shahed,REC,1395,203

Health conditions studied

1

Description of health condition studied

Hypercholesterolemia

ICD-10 code

E78.0

ICD-10 code description

Pure hypercholesterolemia

Primary outcomes

1

Description

Serum Low Density Lipoprotein- Cholesterol Level

Timepoint

Before the intervention, the end of the 4th & 8th week
intervention

Method of measurement

Blood sample

2

Description

Serum High Density Lipoprotein- Cholesterol Level

Timepoint

Before the intervention, the end of the 4th & 8th week
intervention

Method of measurement

Blood sample

3

Description

Serum Total Cholesterol Level

Timepoint

Before the intervention, the end of the 4th & 8th week
intervention

Method of measurement

Blood sample

4

Description

Serum Triglyceride Level

Timepoint

Before the intervention, the end of the 4th & 8th week
intervention

Method of measurement

Blood sample

5

Description

Added at 2017-11-18: Apptetite

Timepoint

Added at 2017-11-18: Before intervention and at the end
of study

Method of measurement

Added at 2017-11-18: VAS questionnaire

Secondary outcomes

1

Description

Serum Glutamic Pyruvic Teransamins

Timepoint

Before the intervention, the end of the 4th & 8th week intervention

Method of measurement

Blood sample

2

Description

Serum Glutamic Oxaloacetic Transaminase

Timepoint

Before the intervention, the end of the 4th & 8th week intervention

Method of measurement

Blood sample

3

Description

Fasting Blood Sugar

Timepoint

Before the intervention, the end of the 4th & 8th week intervention

Method of measurement

Blood sample

4

Description

Serum Blood Urea Nitrogen Level

Timepoint

Before the intervention, the end of the 4th & 8th week intervention

Method of measurement

Blood sample

5

Description

Serum Creatinine Level

Timepoint

Before the intervention, the end of the 4th & 8th week intervention

Method of measurement

Blood sample

6

Description

Added at 2017-11-18: Sleep disorders

Timepoint

Added at 2017-11-18: Before intervention and at the end of study

Method of measurement

Added at 2017-11-18: Sleep questionnaire

Intervention groups

1

Description

Intervention 1: The intervention group in addition to Standard Treatment (a training course in lifestyle & 10 mg Atorvastatin tablets), daily intake of 40 mg pickled capers with meals for lunch and dinner.

Category

Treatment - Drugs

2

Description

Intervention 2: Control group, Standard Treatment (a training course in lifestyle & 10 mg Atorvastatin tablets)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Education & Treatment Center Of Valiasr

Full name of responsible person

Saeed Sardari

Street address

Sheikh Fazlullah Nuri highway, Valiasr Square, Education & Treatment Center Of Valiasr

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University

Full name of responsible person

Zahra Kiasalari

Street address

Shahed University, in Front of the Shrine of Imam Khomeiny , Persian Golf Freeway

City

Tehran

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, Shahed University

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*

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Full name of responsible person

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Ph.D Student in Iranian Traditional Medicine

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City

Tehran

Postal code**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*