

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Study of the Effect of (Thymbra Spicata) plant on Blood Lipids Profile reduction in Human.

Protocol summary

Study aim

Study of The Effect of (Thymbra Spicata) plant on Blood Lipids Profile reduction in Human.

Design

This study is a nonblinded clinical trial. The study population will be included all patients with hyperlipidemia who refer to the office of one of the doctors in Kermanshah. 104 eligible patients will be selected conveniently and randomly assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted in a private medical office in the city of Kermanshah, is a non-blinded one. At the beginning of the study, 10 ccs of blood samples were taken from the patients, and then the lipid profile level of them will be measured using a spectrophotometric method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a cholesterol level greater than 220 and triglycerides greater than 200 mg / dL

Exclusion criteria: Patients with metabolic diseases such as diabetes; Taking any other antihyperlipidemic medication by the patient

Intervention groups

the intervention group in addition to atorvastatin will receive Thymbra Spicata plant daily in packaged leptons as herbal tea. The control group only will receive atorvastatin daily.

Main outcome variables

Blood Lipids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N151**

Registration date: **2020-06-23, 1399/04/03**

Registration timing: **prospective**

Last update: **2020-06-23, 1399/04/03**

Update count: **0**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of (Thymbra Spicata) plant on Blood Lipids Profile reduction in Human.

Public title

The Effect of (Thymbra Spicata) plant on Blood Lipids Profile reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with a cholesterol level greater than 220 and triglycerides greater than 200 mg / dL

Exclusion criteria:
Patients with metabolic diseases such as diabetes Taking any other antihyperlipidemic medication by the patient

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into two groups of 52. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

Blinding (investigator's opinion)
Not 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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-10-15, 1398/07/23

Ethics committee reference number

ir.kums.rec.1399.175

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

Primary outcomes

1

Description

Blood Lipids

Timepoint

Beginning of study and end of study (2 months later)

Method of measurement

laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group in addition to atorvastatin will receive Thymbra Spicata plant daily in packaged leptons as herbal tea.

Category

Treatment - Drugs

2

Description

The control group only will receive atorvastatin daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal clinic

Full name of responsible person

Mohammad Saber Azizi

Street address

Ejlaliyeh building, Shahr-dari parking

City

Kermanshah

Province

Kermanshah

Postal code

6714813142

Phone

+98 83 3725 6731

Email

www.mohamadsaberazizi.1994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Saber Azizi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 4618

Email

www.mohamadsaberazizi.1994@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Amir Kiani

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Toxicology

Street address

School of Pharmacy, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 4618

Email

www.amir1kiani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Saber Azizi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 4618

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 15-day timeframe

Comments