Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+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, Shahrdari parking

City
Kermanshah

Province
Kermanshah

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6714813142

Phone

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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
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+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
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Person responsible for updating data

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Pharmacy student
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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