

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of curcumin bergamot supplementation on fasting triglyceride levels in patients with hypertriglyceridemia taking statin: A randomized double-blind clinical trial

Protocol summary

Study aim

Determining the effect of curcumin bergamot supplement on blood triglyceride

Design

Clinical trial, randomized, double-blind, randomized control group of 40 patients. Randomization is done using a valid website and 4-block method.

Settings and conduct

This clinical trial will be performed in the special clinic of Sedigheh Tahereh Hospital. Curcumin bergamot and placebo are given to the patient in exactly the same packages. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Age 18 to 65 years Fasting blood triglycerides above 150 mg / dL Taking statins

Intervention groups

Intervention group Capsules containing curcumin and bergamot each contain 100 mg of curcumin and 200 mg of bergamot once a day. Control group 1 capsule each containing 300 mg of lactose

Main outcome variables

Fasting blood glucose, fasting blood TG, fasting blood Cholesterol, fasting blood LDL, fasting blood HDL

General information

Reason for update

Due to the outbreak of COVID-19, the implementation of the project is delayed. In addition, some problems in providing supplements and problems regarding budget allocation caused this project delay. Personal problems of some colleagues in performing clinical procedures forced us to recruit new colleagues to perform the project.

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071314521N4**

Registration date: **2017-03-02, 1395/12/12**

Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**

Update count: **1**

Registration date

2017-03-02, 1395/12/12

Registrant information

Name

Amirhossein Sahebkar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1882 9260

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2022-05-04, 1401/02/14

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of curcumin bergamot supplementation on

fasting triglyceride levels in patients with hypertriglyceridemia taking statin: A randomized double-blind clinical trial

Public title

Curcumin and hypertriglyceridemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years Fasting serum TG>150 mg/dl Using Statin drugs

Exclusion criteria:

Unwillingness to participate in the study Sensitivity to herbal supplements

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a reputable random number generation website. (Random number generation website: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>)

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double blinded so that the researcher and the subjects will not know which group they belong to. For blinding, curcumin bergamot and placebo capsules are prepared in the same shape, color, and size. These capsules are coded by someone other than the researchers (A and B) and then the capsules are given to patients. Until the end of the study and after analyzing the data, researchers will not know about the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad, Daneshgah Street, Ghoreishi Bilding

City

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Province

Razavi Khorasan

Postal code

91779-48564

Approval date

2016-11-02, 1395/08/12

Ethics committee reference number

IR.MUMS.fm.REC.1395.102

Health conditions studied**1****Description of health condition studied**

Hypertriglyceridemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridaemia

Primary outcomes**1****Description**

Triglycerides

Timepoint

before the intervention

Method of measurement

enzymatic experimental kit

Secondary outcomes**1****Description**

FBG

Timepoint

2 months after the intervention

Method of measurement

enzymatic experimental kit

2**Description**

Insulin

Timepoint

2 months after the intervention

Method of measurement

radioimmunoassay experimental kit

3**Description**

Total cholesterol

Timepoint

2 months after the intervention

Method of measurement

enzymatic experimental kit

4**Description**

HDL-C

Timepoint

2 months after the intervention

Method of measurement

enzymatic experimental kit

5**Description**

LDL-C

Timepoint

2 months after the intervention

Method of measurement

enzymatic experimental kit

6**Description**

HS-CRP

Timepoint

2 months after the intervention

Method of measurement

ELISA experimental kit

7**Description**

Body mass index

Timepoint

2 months after the intervention

Method of measurement

weight (kg) / height² (m)

Intervention groups**1****Description**

Intervention 1 The participants will be asked to take one capsule/day containing 100 mg curcuminoids and 200 mg bergamot, which was contained in an unlabeled for a period of 8 weeks.

Category

Treatment - Drugs

2**Description**

Intervention 2 The placebo capsules containing lactose which will used orally for a period of 8 weeks. .

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospital

Full name of responsible person

Amirhosein Sahebkar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafagodi

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Mashhad, Azadi Square, Pardis of Ferdousi University, Department of pharmaceutics, 91775-1365, Tel; 00985168823255-65

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amirhosein Sahebkar

Position

PhD in Pharmaceutical Biotechnology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document
Study information will be published after the individuals
are unidentified and after the project is completed.
When the data will become available and for how long
Access period starts six months after the results are
published
To whom data/document is available
Researchers working in academic and scientific
institutions
Under which criteria data/document could be used

For further analysis

From where data/document is obtainable

Amirhossein Sahebkar sahebkar@mums.ac.ir

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

After reviewing the request and making it fully clear

about the purposes of using the data, the data will be

provided
Comments