

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The first phase of clinical trial of of carvacrol to evaluate the safety and tolerability of the substance in humans

Protocol summary

Summary

Objective: Investigation of side effects of carvacrol and its safety and tolerance in humans as named first phase of clinical trial Study design: Non randomize, not blind, without control and placebo, first phase of clinical trial Method: In this study, forty healthy volunteers divided into two groups and each group of twenty people. In the first group one mg/kg of carvacrol and the second group two mg/kg of carvacrol daily as capsules in three servings for one month will be prescribed. The blood and urine samples were taken before and after eating capsules. Main conditions of entry and departure of participants: Inclusion criteria: Physical and mental health and no history of serious illness, the age limit from 20 to 60 years. Exclusion criteria: cardiovascular diseases, brain and vascular disease, malignancy, chronic inflammatory diseases, autoimmune disorders, psychiatric disorders, metabolic diseases, endocrine disorders, other underlying diseases other than those mentioned. Interventions: one and two mg/kg of carvacrol daily as capsules in three servings for one month Main outcome variables: the measurement of biochemical, hormonal and blood factors

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080429191N1**

Registration date: **2016-11-19, 1395/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-19, 1395/08/29

Registrant information

Name

Vahideh Ghorani Sirjani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8565

Email address

ghoranisv921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The first phase of clinical trial of of carvacrol to evaluate the safety and tolerability of the substance in humans

Public title

Investigation of side effects of carvacrol in humans

Purpose

Other

Inclusion/Exclusion criteria

Main conditions of entry to study: Physical and mental health; no history of serious illness; the age limit from 20 to 60 years; write informed consent Main condition of exclusion from study: cardiovascular diseases; brain and vascular disease; malignancy; chronic inflammatory diseases; autoimmune disorders; psychiatric disorders;

metabolic diseases; endocrine disorders; other underlying diseases other than those mentioned; one tends to withdraw from the study; drug intolerance; drug use by participants during the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

2

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ghoreishi Building, Daneshgah street

City

Mashhad

Postal code

-

Approval date

2015-12-27, 1394/10/06

Ethics committee reference number

IR.MUMS.REC.1394.610

Health conditions studied

1

Description of health condition studied

Healthy volunteers

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Biochemical factors

Timepoint

Before and one month after intervention

Method of measurement

Device analysis

2

Description

hormonal factors

Timepoint

Before and one month after intervention

Method of measurement

Device analysis

3

Description

Blood factors

Timepoint

Before and one month after intervention

Method of measurement

Device analysis

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Carvacrol, Capsules contain 30 mg carvacrol, three times per day for one month

Category
Treatment - Drugs

2

Description
Carvacrol, Capsules contain 47 mg carvacrol, three times per day for one month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad University of Medical Sciences

Full name of responsible person
Vahideh Ghorani Sirjani

Street address
School of Medicine, Ferdowsi university campuse, Azadi Square

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Department of pharmaceuticals and panotechnology, School of Pharmacy, Ferdowsi university campuse, Azadi Square

City
Mashhad

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, Mashhad University of Medical Sciences

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

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Vahideh Ghorani Sirjani

Position
Pharmaceutical Sciences PhD Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Department of Physiology, School of Medicine, Mashhad University of Medical Sciences

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Person responsible for updating data

Contact

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Position
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Other areas of specialty/work
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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