

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of Captophyte compound in comparison with Captopril alone on blood pressure in patients with essential hypertension

Protocol summary

Summary

Objectives: control of essential hypertension with captophyte and assess the pharmacogenomics of it.
Design: a randomized controlled trial is designed. Setting & conduct: Patients with primary diagnosis of essential hypertension, and after obtaining informed written consent, 10 ml of blood is taken for serum chemistry including (TG, Chol, LDL, HDL, beta carotene) and molecular studies (expression of ACE, ACE2, AGTR, AGTR2, AGT, NOS3 and genotyping for single nucleotide polymorphisms of rs1799752, rs2106809, rs5186, rs699, rs1799983) are supplied with Captophyte. Inclusion criteria: essential hypertension; age of 20 - 55 years and no response to diet and exercise in pre hypertension state. Exclusion criteria: one or more of the following: Creatinine levels > 1.5 mg/dl; elevated liver enzymes; intake of any of the anti-hypertensive medications due any other underlying medical causes; concurrent intake of any medications having hepatic metabolism (with super enzymes of cytochrome p450 including CYP2D6 (i.e. imipramine, fluoxetine, and ...). CYP3A4 (clarithromycin, erythromycin, cimetidine, and ...) which metabolize most of BB, CCB, ACEI, ARB; medication with warfarin; other cardiovascular complications such as angina pectoris, IHD, hypertensive crisis, or cerebrovascular accidents such as TIA, or stroke which require CCB, BB, ACE; GI disturbances; allergic reactions; immunologic reactions; unwillingness to participate in the study; death of the patient. Captophyte (2.025 g) is administered three times daily in the control group and Captopril 25 mg three times daily combined with placebo is supplied to control group. The patients are followed up weekly. Main outcome is determined by change in blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020110326N2**

Registration date: **2015-09-25, 1394/07/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-25, 1394/07/03

Registrant information

Name

Tasnim Eghbal Eftekhari

Name of organization / entity

Hormozgan University of Medical Sciences,
Department of Research and Technology

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research & Technology Hormozgan
University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Captophyte compound in comparison with

Captopril alone on blood pressure in patients with essential hypertension

Public title

Efficacy of Captophyte compound in comparison with Captopril alone on blood pressure in patients with essential hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: essential hypertension; age of 20 - 55 years and no response to diet and exercise in prehypertension state. Exclusion criteria: one or more of the following: Creatinine levels > 1.5 mg/dl; elevated liver enzymes; intake of any of the anti-hypertensive medications (nitrates, beta blockers, anhydrase carbonic inhibitors, calcium channel blockers, diuretics and angiotensin receptor blocker) due any other underlying medical causes; concurrent intake of any medications having hepatic metabolism (with super enzymes of cytochrome p450 including CYP2D6 (i.e. imipramine, fluoxetine, promethazine, celcoxib, hydroxyzine, citalopram, dextrometorphan, codeine, ondansetron, tamoxifen, tarmadol). CYP3A4 (clarythromycin, erythromycin, cimetidine, carbamazepine, phenytoin, phenobarbital, rifampin, corticosteroids, atorvastatin, benzodiazepines, and haloperidol) which metabolize most of BB, CCB, ACEI, ARB; medication with warfarin; other cardiovascular complications such as angina pectoris, IHD, hypertensive crisis, or cerebrovascular accidents such as TIA, or stroke which require CCB, BB, ACE; GI disturbances; allergic reactions; immunologic reactions; unwillingness to participate in the study; death of the patient.

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Random number generator table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hormozgan University Ethics Committee

Street address

Shahid Mohammadi hospital, Department of research & Technology, Ethics Committee

City

Bandar-e Abbas

Postal code

7919915519

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

3-HEC-94-6-3

Health conditions studied

1

Description of health condition studied

Essential Hypertesion

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

Every week for 28 days

Method of measurement

Measuring blood pressure with mercury sphygmomannometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Captophyte compound divided in two equal 2g doses of red algae and combined with captopril 25 mg tablets in a capsule (Captophyte capsule) three times daily for 28 days.

Category

Treatment - Drugs

2

Description

Control group: 25 mg captopril combined with placebo

(from DANA pharmaceuticals) is used for 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Dr Hossein Farshidi

Street address

Cardiovascular Research Center, Shahid Mohammadi hospital, Jomhouri Blvd

City

Bandar-e Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology,
Hormozgan University of Medical Sciences

Full name of responsible person

Dr Abdolazim Nejatizadeh

Street address

Shahid Mohammadi Hospital, Department of research
& technology, Jomhouri Blvd

City

Bandar-e Abbas

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 & Technology, Hormozgan 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

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Seyedeh Tasnim Eghbal Eftekhari

Position

PhD Candidate

Other areas of specialty/work

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Name of organization / entity

Hormozgan University of Medical Sciences,

Full name of responsible person

Dr Abdolazim Nejatizadeh

Position

Vice Chancellor for Research & Technology; Associate Professor of human genetics

Other areas of specialty/work

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Full name of responsible person

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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