Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the hypotensive effect of amla (Emblica officinalis) and placebo in patients with essential hypertension

Protocol summary

Study aim
Comparison of effect of Amla (Emblica officinalis) with placebo in systolic and diastolic blood pressure in patients with primary hypertension
Design
Seventy patients with mild primary hypertension and meet inclusion criteria, randomly assigned to two groups which are used Amla or placebo together with their previous drugs.
Settings and conduct
The study is conducted in the clinic of hypertension of Heart Research Center of Tabriz University of Medical Sciences. Due to allocation concealment and the similar appearance of Amla and placebo capsules, investigator, participants, and analyzer are blind to the type of interventions.
Participants/Inclusion and exclusion criteria
Patients with mild primary hypertension taking up to two antihypertensive drugs who do not have any hypertensive complications.
Intervention groups
Amla capsule (500 mg powder of dried fruit) 3 times/day after meal
Main outcome variables
Systolic blood pressure; diastolic blood pressure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090527001957N7**
Registration date: **2018-03-23, 1397/01/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-23, 1397/01/03**
Update count: **0**
Registration date
2018-03-23, 1397/01/03

Registrant information
Name
Fataneh Hashem Dabaghian
Name of organization / entity
Research Institute for Islamic and Complementary Medicine
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-10-01, 1396/07/09
Expected recruitment end date
2018-10-01, 1397/07/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the hypotensive effect of amla (Emblica officinalis) and placebo in patients with essential hypertension

Public title
hypotensive effect of amla (Emblica officinalis)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
SBP>=140 mmHg SBP>=150 mmHg in 60 year old or

older patients DBP>=90 mmHg

Exclusion criteria:

SBP>180 mmHg DBP>110 mmHg secondary hypertension hypertensive encephalopathy Hypertensive retinopathy grade 3,4 Acute cerebrovascular accident Acute coronary syndrome decompensated congestive heart failure creatinin > 1.5 times more than normal limit ALT> 3 times more than normal limit diabetic complications coagulopathy use of anticoagulants and anti platelet drugs use of NSAIDS platelet<100000

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used and blocks are selected randomly using the table of random numbers. Allocation concealment will be carried out using Sealed envelops.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Amla and placebo are prepared in similar capsules, therefore participants during the trial, data collectors, outcome assessors, analyzer and manuscript writers are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Junction of Sheikh Fazlollah and Himmat freeway, next to Milad tower, Iran Unuiversity of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1145847111

Approval date

2016-12-10, 1395/09/20

Ethics committee reference number

IR.IUMS.REC 1395.95-02-116-29004

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

systolic blood pressure

Timepoint

before the intervention, at the end of the first and second month after intervention

Method of measurement

mercury barometer

2

Description

diastolic blood pressure

Timepoint

before the intervention, at the end of the first and second month after intervention

Method of measurement

mercury barometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Amla capsule(500 mg) 3 times/day after meal

Category

Treatment - Drugs

2

Description

Control group: placebo capsul 3 times /day after meal

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Heart Center

Full name of responsible person
Samad Ghaffari

Street address
Daneshgah St., Shahid Madani hospital, Heart research center

City
Tabriz

Province
East Azarbaijan

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ghafaris@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for Islamic and Complementary Medicine

Full name of responsible person
Ali Ghobadi

Street address
No: 9, Pirnia alley, Lalehzar St., Jomhuri Ave., Tehran

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alighobadi56@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Research Institute for Islamic and Complementary Medicine

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
Research Institute for Islamic and Complementary Medicine

Full name of responsible person
Fataneh Hashem-Dabaghian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Community medicine

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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
No - There is not a plan to make this available

Title and more details about the data/document
Collected data can be shared without the name and characteristics of the participants.

When the data will become available and for how long
Access to data is possible 6 months after the publication of the article

To whom data/document is available
Data will only be available to researchers in academic institutions

Under which criteria data/document could be used
There is no limit to the data analysis

From where data/document is obtainable
Applicants can email to the following address: fataneh.dabaghian@yahoo.com

What processes are involved for a request to access data/document
Maximum one week after receiving email

Comments