

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of Barij blood pressure syrup products in patients with hypertension: a double blind randomized placebo controlled trial

Protocol summary

Study aim

This study aims to evaluate the efficacy of Barij syrup in hypertensive patients. informed consent (blinded study). Therefore patients aren't aware of their therapeutic group they will be assigned. In addition, neither patients nor medical staff will be aware of the type of oils in the container (Barij syrup or placebo). Only the researcher is aware of the code written on the container of the syrups ; so, this study is a double-blind, parallel clinical trial. Hypertensive patients with SBP /DBP \geq 140/90 mmHg were eligible for inclusion. fifty of patients attending the Shahid beheshti who meet our inclusion criteria will take part in this study. By using random numbers (created by throwing coin and dice) subjects will randomly allocate to one of two experimental groups: a placebo and a test group. Thus, 25 cases in each treatment arm receive placebo or Barij syrup . In the intervention group, 30 ml oral Barij syrup is administered daily for 3 months . Patients in the control group receive placebo in the same way. Systolic and diastolic pressure (during intervention) will be checked as primary outcomes.

Design

Randomised controlled clinical trial and double blind, parallel study

Settings and conduct

This study is conducted at Shahid Beheshti Hospital in Qom and is blinded by placebo

Participants/Inclusion and exclusion criteria

Inclusion criteria :Patient with stage I hypertension (Systolic Blood Pressure 140-159 mmHg, Diastolic Blood Pressure) 90-99 mmHg) Exclusion criteria:Pregnant women or women planning to get pregnant, Being allergic to Barij syrups, Suffering from intestinal diseases such as Crohn's disease, colitis, peptic ulcer, irritable bowel syndrome (IBS), History of myocardial infarction, coronary bypass surgery during last 6 month

Intervention groups

Patient with stage 1 hypertension

Main outcome variables

Systolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170112031893N1**

Registration date: **2018-04-07, 1397/01/18**

Registration timing: **prospective**

Last update: **2018-04-07, 1397/01/18**

Update count: **0**

Registration date

2018-04-07, 1397/01/18

Registrant information

Name

Hossein Yusefi

Name of organization / entity

Qom University of medical science

Country

Iran (Islamic Republic of)

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+98 25 3886 0146

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Barij blood pressure syrup products in patients with hypertension: a double blind randomized placebo controlled trial

Public title

Evaluation of Barij blood pressure syrup products in patients with hypertension

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with stage I hypertension (Systolic Blood Pressure (SBP) 140-159 mmHg, Diastolic Blood Pressure (DBP) 90-99 mmHg) and not using a particular anti-hypertensive therapy

Exclusion criteria:

Pregnant women or women planning to get pregnant
Being allergic to Barij syrups
Suffering from intestinal diseases such as Crohn's disease, colitis, peptic ulcer, irritable bowel syndrome (IBS)
History of myocardial infarction; coronary bypass surgery during last 6 month

Age

From **25 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by Throwing coin and dice

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients, statistical analyst and physicians are not aware of the allocation of drugs and placebo, and someone outside the group is aware of the allocation of treatment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

Street address

Vice chancellor for research of Qom University of Medical Sciences, Safashar road, Qom, Iran

City

qom

Province

Ghoum

Postal code

87366-37169

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

IR.MUQ.REC.1396.135

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

Prior to study, second week, fourth week, eighth week and at the end of study

Method of measurement

In mmHg using mercuric manometer

Secondary outcomes

empty

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

Intervention group: Barij syrup. (A natural combination of chicory, tangerine, malt extract, sesame, sour lemon, sweet almond produced by Barij company) 30 ml oral Barij syrup is administered daily for three months

Category

Treatment - Drugs

2**Description**

Control group: Placebo syrup 30 ml daily for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Seyyed fakhreddin hejazi

Street address

Clinical Research Development Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Sq, Qom, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Essence Company

Full name of responsible person

Mohsen Taghizadeh

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Barij Essence Company, Kashan

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taghizadeh_m@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Essence Company

Proportion provided by this source

75

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

2

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

hossein saghafi

Street address

Number 83, Alley 4, Alley 1.1, Safashahr Street

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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

Ghous University of Medical Sciences

Proportion provided by this source

25

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

Ghous University of Medical Sciences

Full name of responsible person

Hossein moradi

Position

Professor of Iranian traditional medicine

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

With attention due to the type of study and publication of the article, there was no need to mention this

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available