

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the effect of quercetin and berberine on laboratory and functional indices of the heart and pulmonary vessels in patients with pulmonary arterial hypertension

Protocol summary

Study aim

Investigation of the effect of quercetin and berberine on laboratory and functional indices of the heart and pulmonary vessels in patients with pulmonary arterial hypertension

Design

140 patients with pulmonary arterial hypertension (PAH) were randomly divided into 7 groups including PAH, PAH + Placebo, PAH + Quercetin (QS) 250, PAH+QS500, PAH+ Berberin (BBR) 500, PAH+BBR1000 and PAH+QS+BBR. And the phase 3 clinical trial is being investigated.

Settings and conduct

The study is conducted in Afzalipur Hospital, Kerman, and double blinding including the researcher and the patient is done by coding the drugs.

Participants/Inclusion and exclusion criteria

In this study, based on the information contained in the checklists, 140 patients with pulmonary artery hypertension and over 10 years of age were selected from among the patients who referred to the heart or lung department of Afzalipur Hospital by the colleagues of the heart or lung specialist. Randomly, they are placed in 7 groups of 20 people who are homogenized in terms of age, gender and BMI. How to calculate the sample size is explained below. Exclusion criteria include liver, kidney, diabetes, specific diseases such as cancer and known vascular diseases except pulmonary artery hypertension (such as valvular diseases and left heart failure).

Intervention groups

In this study, daily doses of 250 and 500 mg of quercetin and 500 and 1000 mg of berberine are given to patients with PAH.

Main outcome variables

Right ventricular systolic pressure ,Right ventricular diastolic pressure . Partial pressure of oxygen ,

Creatinine, Serum glutamic-pyruvic transaminase , serum glutamic – oxaloacetic transaminase, Alkaline Phosphatase, Triglyceride, High Density Lipoprotein, Cholesterol, Low Density Lipoprotein ,Superoxide dismutase, Glutathione Peroxidase, Malondialdehyde, Tumor necrosis factor alpha, Interleukin (IL) -8, IL-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230220057462N1**

Registration date: **2023-03-18, 1401/12/27**

Registration timing: **prospective**

Last update: **2023-03-18, 1401/12/27**

Update count: **0**

Registration date

2023-03-18, 1401/12/27

Registrant information

Name

Hamid Najafipour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of quercetin and berberine on laboratory and functional indices of the heart and pulmonary vessels in patients with pulmonary arterial hypertension

Public title
The effect of quercetin and berberine on pulmonary arterial hypertension

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with pulmonary artery hypertension
Exclusion criteria:
Liver disease kidney Diseases diabetes Specific diseases such as cancer and known vascular diseases

Age
From **10 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are divided into seven groups of 20 people according to the order of referral and after meeting the entry criteria and after obtaining the consent form according to balanced blocked randomization. Block randomization is a commonly used technique in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms, especially when the sample size is small.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main drug and the placebo are coded by a person who is not aware of the study. The specialist doctor introduces the patient to receive the medicine. The distributor (nurse), who is unaware of the codes, randomly gives the medicines to the patients. After taking the medicine, the patient goes to the doctor and is examined. The doctor gives the results to a researcher who is not aware of the codes for analysis.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Medical Faculty, Kerman University of Medical Sciences Blvd. 22 Bahman, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7619813159

Approval date
2023-02-06, 1401/11/17

Ethics committee reference number
IR.KMU.REC.1401.514

Health conditions studied

1

Description of health condition studied
pulmonary arterial hypertension

ICD-10 code
I27.2

ICD-10 code description
Other secondary pulmonary hypertension

Primary outcomes

1

Description
People with pulmonary artery peak systolic pressure >35 mm Hg

Timepoint
The first and last days of study

Method of measurement
Echocardiography

Secondary outcomes

1

Description
Arterial oxygen saturation percentage

Timepoint

The first and last days of study

Method of measurement

Pulse oximeter

2**Description**

High density lipoprotein

Timepoint

The first and last days of study

Method of measurement

laboratory test

3**Description**

Cholesterol

Timepoint

The first and last days of study

Method of measurement

laboratory test

4**Description**

Triglyceride

Timepoint

The first and last days of study

Method of measurement

laboratory test

5**Description**

Heart rate

Timepoint

The first and last days of study

Method of measurement

Pulse oximeter

6**Description**

The diameter of the right ventricular cavity at the end of systole (RVESd)

Timepoint

The first and last days of study

Method of measurement

Echocardiography

7**Description**

The size of the diameter of the right ventricular cavity at the end of diastole

Timepoint

The first and last days of study

Method of measurement

Echocardiography

8**Description**

The percentage of the volume of blood that leaves the ventricle in each beat

Timepoint

The first and last days of study

Method of measurement

Echocardiography

9**Description**

Shortening Fraction

Timepoint

The first and last days of study

Method of measurement

Echocardiography

10**Description**

Pulmonary Velocity Acceleration time

Timepoint

The first and last days of study

Method of measurement

Echocardiography

11**Description**

pulmonary vessel resistance

Timepoint

The first and last days of study

Method of measurement

Echocardiography

12**Description**

Tricuspid regurgitation velocity

Timepoint

The first and last days of study

Method of measurement

Echocardiography

13**Description**

The level of superoxide dismutase

Timepoint

The first and last days of study

Method of measurement

The relevant kit

14**Description**

The level of glutathione peroxidase

Timepoint

The first and last days of study

Method of measurement

The relevant kit

15

Description

The amount of malondialdehyde

Timepoint

The first and last days of study

Method of measurement

The relevant kit

16

Description

Interleukin 6

Timepoint

The first and last days of study

Method of measurement

Elisa kit

17

Description

Tumor necrosis factor alpha

Timepoint

The first and last days of study

Method of measurement

Elisa kit

18

Description

Creatinine

Timepoint

The first and last days of study

Method of measurement

laboratory test

19

Description

serum glutamic-pyruvic transaminase

Timepoint

The first and last days of study

Method of measurement

laboratory test

20

Description

alanine aminotransferease

Timepoint

The first and last days of study

Method of measurement

laboratory test

21

Description

Serum glutamic oxaloacetic transaminase

Timepoint

The first and last days of study

Method of measurement

laboratory test

Intervention groups

1

Description

Control group: People included in this study group have RVSP above 35 mmHg and receive their classical treatments during the study period.

Category

Treatment - Drugs

2

Description

Intervention group 1: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, will receive a placebo capsule daily during the period of the pilot study.

Category

Placebo

3

Description

Intervention group2: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, during the period that is obtained in the pilot study, receive one QS oral supplement capsule at a dose of 250 mg/day.

Category

Treatment - Drugs

4

Description

Intervention group 3: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, during the period that is obtained in the pilot study, they receive a QS oral supplement capsule at a dose of 500 mg/day.

Category

Treatment - Drugs

5

Description

Intervention group 4: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, during the period that is obtained in the pilot study, daily receive one berberine capsule with a dose of 500 orally.

Category

Treatment - Drugs

6

Description

Intervention group 5: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, during the period that is obtained in the pilot study, daily receive a berberine capsule with a dose of 1000 orally.

Category

Treatment - Drugs

7

Description

Intervention group 6: In this group, people with pulmonary artery hypertension, in addition to receiving classic drugs, during the period that is obtained in the pilot study, daily receive one capsule of QS with a dose of 250 mg and one capsule of berberine with a dose of 500 mg orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Mohamad mehdi Bagheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bam University of Medical Sciences

Full name of responsible person

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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

Bam University of Medical Sciences

Proportion provided by this source

46

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

2

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman University of Medical Sciences

Proportion provided by this source

24

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

3

Sponsor

Name of organization / entity

Physiology research center

Full name of responsible person

Hamid Najafipour

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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
 Physiology research center
Proportion provided by this source
 30
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
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Full name of responsible person
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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

At the time of publication of the article and after that based on the reasonable request and the needs of other researchers, study variables and statistical tests used to compare the studied groups, as well as information about the participants and the study protocol and other information, will be provided to the requester.

When the data will become available and for how long

Unlimited after publication of articles

To whom data/document is available

Other researchers in the studied field

Under which criteria data/document could be used

Data sharing will be done in the form of a joint proposal

From where data/document is obtainable

By email to the corresponding author

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

The applicant contacts the corresponding author via e-mail and submits his request, and the corresponding author provides them after consulting with other colleagues.

Comments