Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 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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Iran (Islamic Republic of)

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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
Street address
Jahad Blvd, Ebn Sina Avenue
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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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7661771967
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Research_bam@yahoo.com
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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Position
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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