Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Dapagliflozin on Cardiovascular Outcomes and Quality of Life in Pulmonary Arterial Hypertension Patients

Protocol summary

Study aim
Determining the effect of dapagliflozin on Brain natriuretic peptide in patients with pulmonary arterial hypertension groups

Design
A controlled, parallel-group, triple-blind, randomized, phase 2 clinical trial on 100 patients. Randomization is done by RIT randomization software.

Settings and conduct
This study is a phase two clinical trial. Pulmonary arterial hypertension patients referring to PH clinic in Masih Daneshvari Hospital after screening according to inclusion and exclusion criteria would be divided into two groups of intervention and control. Data collection form will be fulfilled at baseline and after 3 months. The results will be collected and analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Age ≥ 18 years • Diagnosis of group 1 or group 4 PAH • NYHA functional class above one Exclusion criteria: • SGLT2i treatment within 6 months prior to study entry • eGFR less than 30 ml/min/m2 • Severe liver dysfunction • Severe urinary or vaginal infection

Intervention groups
Patients are divided into two groups receiving dapagliflozin with a dose of 10 mg daily for 3 months and a control group, including 50 patients in each arm. The intervention group takes one tablet daily for 3 months. The control group takes a placebo pill daily for 3 months.

Main outcome variables
Pro- Brain natriuretic peptide (Pro- BNP)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200209046427N2**
Registration date: **2023-08-18, 1402/05/27**
Registration timing: **prospective**

Last update: **2023-08-18, 1402/05/27**
Update count: **0**

Registration date
2023-08-18, 1402/05/27

Registrant information

Name
Shadi Shafaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2712 2522

Email address
shafaghishadi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Dapagliflozin on Cardiovascular Outcomes and Quality of Life in Pulmonary Arterial Hypertension Patients

Public title
Dapagliflozin in Pulmonary Arterial Hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age > or = 18 PAH, class of 1 & 4 based on guideline In the case of group 4 PH, the patient should not be candidate for endarterectomy or balloon angioplasty during project NYHA Functional Class >1 Clinically stable patients on pulmonary vasodilator treatment and treatment duration of at least four weeks. Clinical stability defined as stable symptoms without progression as assessed by treating clinician and without the need for unplanned hospital admissions due to worsening PAH within three months of screening. Literacy Informed consent

Exclusion criteria:

Allergy to SGLT2i treatment with SGLT2i in last 6 months PAH 2, 3, 5 eGFR <30 Severe liver dysfunction (Child-Pugh Class C) Lung transplant candidate Type 1 diabetes Severe Urinary or vaginal infection

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is designed to randomize subjects into groups that result in equal sample sizes and to ensure a balance in sample size across groups over time. Patients will be entered into the study groups by simple randomization in a 1:1 ratio (intervention to control ratio) and in blocks of 4. The investigators ensure unpredictability of the allocation sequence and by using a computerized random number generation process. By using this central randomization, the random allocation sequence will remain concealed from those enrolling patients into the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

People involved in the trial including participants(patients), principle investigator particularly investigator initiated trial, healthcare providers (Physicians, nurses, etc.), who care for participants during the trial, data collectors, and outcome assessors and data saftey and monitoring board do not know if the recipient is receiving the actual drug or placebo and all of them are blinded. Dapagliflozin tablets 10 mg from Actover company in both intervention and placebo groups are completely similar in terms of color, shape, smell, size and method of administration. Drugs will be delivered to patient as A or B in the same shape, and nobody knows which of them is true drug and which of them is placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2023-08-13, 1402/05/22

Ethics committee reference number

IR.SBMU.NRITLD.REC.1402.092

Health conditions studied

1

Description of health condition studied

Pulmonary arterial hypertension

ICD-10 code

I27. 0

ICD-10 code description

Primary pulmonary hypertension

Primary outcomes

1

Description

Pro- Brain natriuretic peptide (Pro-BNP)

Timepoint

First day, 3 months later at the randomization time

Method of measurement

Laboratory data (Blood Sample)

Secondary outcomes

1

Description
The 6-minute walk test (6MWT) test
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Treadmill

2

Description
New York Heart Association (NYHA) functional class
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Taking History approved by physician

3

Description
Health Related Quality of Life
Timepoint
First day, 3 months later at the randomization time
Method of measurement
EmPHasis-10 Health Related Quality of life questionnaire

4

Description
Pulmonary arterial pressure (PAP)
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Echocardiography

5

Description
Tricuspid annular plane systolic excursion (TAPSE)
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Echocardiography

6

Description
Tricuspid annular plane systolic excursion (TAPSE) / Pulmonary arterial pressure (PAP)
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Echocardiography

7

Description
Right ventricle (RV) Size
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Echocardiography

8

Description
Pericardial effusion
Timepoint
First day, 3 months later at the randomization time
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: Dapagliflozin (Sodium-glucose co-transporter-2 (SGLT2) inhibitors with a dose of 10 mg/daily from Actover company for 3 months
Category
Treatment - Drugs

2

Description
Control group: Placebo of Dapagliflozin one tablet/daily from Actover company for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Shadi Shafaghi
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Darabad Avenue, Shahid Bahonar roundabout
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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
Shahid Beheshti University of Medical Sciences

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shadi Shafaghi

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Cardiology

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Professor

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Specialist

Other areas of specialty/work
Cardiology

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Person responsible for updating data

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Researcher

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Medical doctor

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General Practitioner

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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

All collected deidentified patient`s documents can be available.

When the data will become available and for how long

Documents files will become available 6 months after publication up to one year

To whom data/document is available

Documents would be available for people working in academic institutions and people working in businesses after applying to receive it.

Under which criteria data/document could be used

Documents would be available according to cause of request.

From where data/document is obtainable

shafaghishadi@yahoo.com Documents would be available according to cause of request. Shadi Shafaghi

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

It is necessary for the applicant to send an e-mail to the researcher and write the reason for requesting access to the data. If confirmed, the information will be sent within a week.

Comments