# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Evaluation of the Effect of Empagliflozin on Clinical Echocardiographic Parameters in Patients with Pulmonary Arterial Hypertension Secondary to COPD: A Randomized Clinical Trial

## Protocol summary

**Study aim**

Determining the effect of empagliflozin on clinical parameters, including echocardiographic indices, functional class, systolic blood pressure, blood oxygen saturation, frequency of hospitalizations, and the number of exacerbations in patients with pulmonary hypertension secondary to chronic obstructive pulmonary disease

**Design**

A phase 2, randomized, controlled clinical trial with parallel-group design, conducted on 72 patients. Randomization was performed using a permuted block method with variable block sizes of 2, 4, and 6.

**Settings and conduct**

This randomized clinical trial will be conducted on 72 patients with COPD and pulmonary arterial hypertension (PAH) who are referred to Hajar and Kashani hospitals. Participants will be randomly assigned, using a permuted block randomization method, into two groups:Intervention group: Standard treatment (bronchodilators ± inhaled corticosteroids) plus Empagliflozin 10 mg once daily for 12 weeks.Control group: Standard treatment only.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Written informed consent to participate in the study, Age over 18 years, Diagnosis of pulmonary hypertension secondary to COPD, Mean pulmonary artery pressure > 20 mmHg, Estimated glomerular filtration rate (eGFR) > 30 mL/min Exclusion Criteria: Active genital infection,Primary (idiopathic) hypertension, Diabetes mellitus, Pre-existing heart failure, Underlying renal failure with serum creatinine ≥ 3 mg/dL, Any hypersensitivity reaction, Angioedema, Acute kidney injury, Ketoacidosis, Urinary tract infection associated with the use of empagliflozin

**Intervention groups**

Intervention group: Standard treatment + Empagliflozin tablet Control group: Standard treatment

**Main outcome variables**

Echocardiographic parameters, functional class, systolic blood pressure, blood oxygen saturation, number of hospitalizations, and frequency of disease exacerbations.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250908067192N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

**Registration date**

2025-10-07, 1404/07/15

**Registrant information**

**Name**

Farank Filsoof

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 38 3222 0016

**Email address**

faranakfilsoof@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-11-12, 1404/08/21

**Expected recruitment end date**

2026-07-11, 1405/04/20

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the Effect of Empagliflozin on Clinical Echocardiographic Parameters in Patients with Pulmonary Arterial Hypertension Secondary to COPD: A Randomized Clinical Trial

**Public title**
Effect of Empagliflozin on Pulmonary Arterial Hypertension Secondary to COPD
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age over 18 years Mean pulmonary arterial pressure above 20 mmHg Glomerular filtration rate above 30 ml/min Written informed consent to participate in the study Diagnosis of pulmonary arterial hypertension secondary to COPD
**Exclusion criteria:**
Presence of active genital infection Primary hypertension,Diabetes mellitusUnderlying heart failure, Underlying renal failure with serum creatinine equal to or greater than 3 mg/dL Pregnancy Any allergic reaction, angioedema, acute kidney injury, ketoacidosis, urinary tract infection caused by empagliflozin
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **72**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Participants will be randomly assigned to two groups—intervention (standard treatment + empagliflozin pill) and control (standard treatment)—based on a random permutation method with random block sizes of 4, 2, and 6 (due to the uncertainty of the last individual in each block).
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shahrekord University of Medical Sciences
**Street address**
University Headquarters, Kashani Blvd, Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8816854633
**Approval date**
2025-02-04, 1403/11/16
**Ethics committee reference number**
IR.SKUMS.MED.REC.1403.115

## Health conditions studied

### 1

**Description of health condition studied**
Pulmonary hypertension secondary to chronic obstructive pulmonary disease
**ICD-10 code**
I27.9
**ICD-10 code description**
Pulmonary heart disease, unspecified

## Primary outcomes

### 1

**Description**
Mean echocardiographic parameters (cardiac output, mean pulmonary artery pressure, pulmonary artery pressure, right ventricular systolic pressure, right ventricular function, pulmonary vascular resistance, cardiac index)
**Timepoint**
Before the intervention and after taking empagliflozin
**Method of measurement**
Echocardiography device

### 2

**Description**
Frequency of pulmonary hypertension activity class
**Timepoint**
Before the intervention and after taking empagliflozin
**Method of measurement**
Questionnaire

### 3

**Description**
Mean systolic blood pressure
**Timepoint**
Before the intervention and after taking empagliflozin
**Method of measurement**
Mercury sphygmomanometer

### 4

**Description**
Mean blood oxygen saturation
**Timepoint**
Before the intervention and after taking empagliflozin
**Method of measurement**
Pulse oximetry device

## Secondary outcomes

### 1

**Description**
Number of hospitalizations
**Timepoint**
After administration of empagliflozin
**Method of measurement**
Checklist

### 2

**Description**
Frequency of COPD exacerbations
**Timepoint**
After administration of empagliflozin
**Method of measurement**
Checklist

## Intervention groups

### 1

**Description**
Intervention group: Standard treatment (Flosalmax inhaler, two puffs every 12 hours; manufactured by Jaber Pharmaceutical Company) plus Empagliflozin 10 mg tablet (manufactured by Abidi Pharmaceutical Company), once daily for 12 weeks
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Standard treatment (Flosalmax inhaler, two puffs every 12 hours; manufactured by Jaber Pharmaceutical Company)
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Hajar hospital
**Full name of responsible person**
Zahra Habibi
**Street address**
Hajar Hospital, Parsart Street, Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8816854633
**Phone**
+98 38 3222 0016
**Fax**
**Email**
faranakfilsoof@gmail.com
**Web page address**

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahre-kord University of Medical Sciences
**Full name of responsible person**
Dr. Akbar Soleimani Babadi
**Street address**
University Headquarters, Kashani Blvd,Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
881685433
**Phone**
+98 38 3222 0016
**Fax**
**Email**
dr.akbarsoleymani@yahoo.com
**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahre-kord 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**
Shahroud University of Medical Sciences
**Full name of responsible person**
Zahra Habibi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Hajar Hospital, Parsart Street, Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8816854633
**Phone**
+98 38 3222 0016
**Fax**
**Email**
habibi.z@skums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahre-kord University of Medical Sciences
**Full name of responsible person**
Zahra Habibi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Hajar Hospital, Parsart Street, Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8816854633
**Phone**
+98 38 3222 0016
**Fax**
**Email**
habibi.z@skums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shahre-kord University of Medical Sciences
**Full name of responsible person**
Zahra Habibi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Hajar Hospital, Parsart Street, Shahrekord
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8816854633
**Phone**
+98 38 3222 0016
**Fax**
**Email**
habibi.z@skums.ac.ir
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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