Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effects of SGLT2 inhibitor drugs in reducing acute COPD attacks and right ventricular function and parameters in non-diabetic patients with chronic obstructive pulmonary disease (COPD) with right ventricular dysfunction and normal left ventricular functio

Protocol summary

Study aim
A review of the effect of SGLT2 inhibitor drugs on the function of right ventricular parameters and reducing acute attacks of COPD in non-diabetic patients with chronic obstructive pulmonary disease. (COPD) with right ventricular dysfunction and normal left ventricular function

Design
This study is a single-blind, single-center, randomized clinical trial with a control group . Ralloc package in STATA.14 software was used for randomization

Settings and conduct
imamhossein hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: smoking patients over 40 years old with a diagnosis of COPD admitted to the hospital and undergoing standard treatment at the time of discharge and control according to the opinion of the lung specialist based on the history and examination of imaging and spirometry in echo Exit criteria: Diabetic patients Kidney failure, GFR<30 Serum potassium >5/2 Liver dysfunction (AST or ALT more than three times the upper limit of normal) and biliary cirrhosis and cholestasis Active malignancy A patient undergoing chemotherapy or immunotherapy Pregnancy and breastfeeding Cardiac output less than 50 more than mild mitral valve insufficiency, more than mild aortic valve insufficiency Left ventricular diastolic failure higher than mild, any valvular stenosis in echo and the presence of other causes of right ventricular failure History of PHTN such as hypothyroid and hyperthyroid and connective tissue diseases and blood diseases such as thalassemia, anemia, tuberculosis, splenectomy and HIV Patients with history of hospitalization in ICU or history of intubation

Intervention groups
Administration of empagliflozin 10 mg to the intervention group

Main outcome variables
Changes in echocardiography criteria Changes in COPD attacks Change in severity of COPD attacks Change in the mortality rate of COPD patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240707062351N1**
Registration date: **2024-10-17, 1403/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-17, 1403/07/26**
Update count: **0**

Registration date
2024-10-17, 1403/07/26

Registrant information

Name
SAMAN KESHVARI ASL

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2025-03-02, 1403/12/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
the effects of SGLT2 inhibitor drugs in reducing acute COPD attacks and right ventricular function and parameters in non-diabetic patients with chronic obstructive pulmonary disease (COPD) with right ventricular dysfunction and normal left ventricular functio

Public title
the effect of empagliflozin on heart function in patients with chronic obstructive pulmonary disease
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
age more than 40 years Having chronic obstructive pulmonary disease based on history, imaging and spirometry by a lung specialist
Exclusion criteria:
Diabetic patients Kidney failure, GFR<30 Serum potassium > 5.2 Liver dysfunction (AST or ALT more than three times the upper limit of normal and biliary cirrhosis and cholestasis) Active malignancy Patient undergoing chemotherapy or immunotherapy Pregnancy and breastfeeding EF<50% History of cardiovascular diseases including more than mild mitral valve insufficiency, more than mild aortic valve insufficiency Left ventricular diastolic failure more than mild, any valvular stenosis in echo and the presence of other causes of right ventricular failureHistory of PHTN such as hypothyroid and hyperthyroid and connective tissue diseases and blood diseases such as thalassemia anemic, tuberculosis, splenectomy and HIV Patients who were hospitalized in the intensive care unit or underwent intubation before the start of the study
Age
From **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible people will be randomly assigned to one of the two drug receiving groups with a ratio of 1:1. Randomization method as permuted block randomization will be based on the sample size in 13 blocks of sizes 2, 4, 6, 8, and 10 using the package "Ralloc" will be done in STATA.14 software. Patients were determined based on the sample size and randomized based on the list of people (along with the research code). specific about each person (will be entered in each group)
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is single blind. The person in charge of data analysis will not be aware of the division of empagliflozin and control group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
South hassan bana Ave
City
Tehran
Province
Tehran
Postal code
1633917516
Approval date
2024-06-18, 1403/03/29
Ethics committee reference number
IR.SBMU.MSP.REC.1403.167

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease
ICD-10 code
J44.1
ICD-10 code description
Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description
The rate of acute attacks of COPD during three months after the intervention by empagliflosine group and control group

Timepoint
During three months from the beginning of the study to the end of the study
Method of measurement
visit,history,checklist

2

Description
Investigation and comparison of severity of acute attacks of COPD during three months after the intervention by empagliflosine group and control group
Timepoint
During three months from the beginning of the study to the end of the study
Method of measurement
visit,history,checklist

3

Description
Investigating and comparing the mortality rate of COPD patients within three months after the intervention, separately from the empagliflosine group and the control group
Timepoint
During three months from the beginning of the study to the end of the study
Method of measurement
visit,history,checklist

4

Description
Investigation and comparison of changes in echocardiographic criteria and RV function in non-diabetic COPD patients during three months after the intervention by groupempagliflosine and control group
Timepoint
The beginning of the study and 3 months after that
Method of measurement
echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Daily use of empagliflozin 10 mg orally manufactured by an Iranian pharmaceutical company for a maximum of 3 months after discharge
Category
Treatment - Drugs

2

Description
Control group: It will include patients who meet the inclusion criteria but do not receive any intervention and are only under standard medical care according toThe clinical trial protocol will be monitored and followed up for a maximum of three months after discharge from the hospital
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
IMAM HOSSEIN HOSPITAL
Full name of responsible person
Saman Keshvari Asl
Street address
Soth Hassan bana
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti 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
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

Saman Keshvari Asl

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Subspecialist

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Email

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable