Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of inhaled verapamil on pulmonary artery systolic pressure in patients with chronic obstructive pulmonary disease hospitalized in Imam Khomeini Hospital, Tehran: a randomized, double-blind clinical trial

Protocol summary

Study aim
Investigating the effect of inhaled verapamil on pulmonary artery systolic pressure in patients with chronic obstructive pulmonary disease

Design
Patients with chronic obstructive pulmonary disease are divided into 2 drug intervention and control groups The clinical trial has a total sample size of 46 patients. The randomization method is based on the randomization table designed based on blocks of 4.

Settings and conduct
In the drug receiving group, verapamil was administered by inhalation in the amount of 10 mg with a dilution of 2.5 mg/ml with a volume of 4 cc by the Ultrasonic Nebulier CUN60 device once every 12 hours for 72 hours and a total of 60 mg. In the placebo group, 4 cc of distilled water (DW) was inhaled every 12 hours for 72 hours, then all patients underwent echocardiography one hour after receiving the last dose. The doctor treating the patient knows how to intervene in patients, but the echocardiologist colleague and the colleague responsible for recording clinical information and echo parameters do not know about the intervention.

Participants/Inclusion and exclusion criteria
Patients with chronic obstructive pulmonary disease and hospitalized in Imam Khomeini Hospital No history of kidney failure, liver failure, pulmonary embolism and congenital heart disease

Intervention groups
Patients with COPD were selected based on GOLD clinical criteria, spirometric characteristics, and the presence of clinical symptoms. Then the patients are divided into two groups receiving inhaled verapamil and placebo.

Main outcome variables
pulmonary artery pressure; EF value; RV size; TAPSE; RVsm; RV FAC; Mean PAP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230804059027N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date
2023-08-12, 1402/05/21

Registrant information

Name
Kazem Gharloghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 4822 7603

Email address
dr.k.gharloghi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-07, 1402/05/16

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of inhaled verapamil on pulmonary artery systolic pressure in patients with chronic obstructive pulmonary disease hospitalized in Imam Khomeini Hospital, Tehran: a randomized, double-blind clinical trial

Public title
Investigating the effect of inhaled verapamil on pulmonary artery systolic pressure in patients with chronic obstructive pulmonary disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with proven chronic obstructive pulmonary disease based on spirometry criteria and patient history Patients with proven chronic obstructive pulmonary disease and hospitalized in Imam Khomeini Hospital

Exclusion criteria:
Valvular heart disease more than moderate Pulmonary valve stenosis History of renal failure History of liver cirrhosis History of pulmonary embolism Congenital heart disease

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups receiving inhaled verapamil and placebo. The method of randomization is based on the randomization table designed on the basis of blocks of 4, so that the patient's doctor knows how to intervene in patients, but the echocardiologist colleague and the colleague responsible for recording clinical information and echo parameters do not know about the intervention.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients with COPD are selected based on GOLD clinical criteria, spirometric characteristics, and the presence of clinical symptoms by respected professors specializing in pulmonary diseases. Then the patients are divided into two groups receiving inhaled verapamil and placebo. The method of randomization is based on the randomization table designed on the basis of blocks of 4, so that the attending physician (clinical caregiver) knows how to intervene in patients, but the echocardiologist colleague and the colleague responsible for recording clinical information and echo parameters as well The co-analysts of the data are not aware of the clinical intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Tehran Uninersity of Medical Sciences

Street address
Imam Khomeini Hospital., Doctor Gharib Street

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2022-11-15, 1401/08/24

Ethics committee reference number
IR.TUMS.IKHC.REC.1401.214

Health conditions studied

1

Description of health condition studied
chronic obsrtuctive pulmonary disease

ICD-10 code
I27.2

ICD-10 code description
Other secondary pulmonary hypertension

Primary outcomes

1

Description
Pulmonary artery systolic pressure reduction

Timepoint
Pulmonary artery systolic pressure was measured by echocardiography at the beginning of the study (before the intervention) and 1 hour after receiving inhaled verapamil.

Method of measurement
Echocardiography device Affiniti 50

Secondary outcomes

1

Description
The increase in oxygen saturation of arterial blood
Timepoint
Arterial blood oxygen saturation is measured before receiving inhaled verapamil (pre-intervention) and 1 hour after the intervention.
Method of measurement
Measurement of arterial blood oxygen saturation is done by finger pulse oximeter

Intervention groups

1

Description
Intervention In the intervention group: with chronic obstructive pulmonary disease hospitalized in Imam Khomeini Hospital in this group, verapamil in the form of inhalation and in the amount of 10 mg with a dilution of 2.5 mg/mL with a volume of 4 cc by Ultrasonic Nebulier CUN60 device once every 12 hours for 72 hours and in A total of 60 mg is prescribed.
Category
Treatment - Drugs

2

Description
Control group: In the control group: patients with chronic obstructive pulmonary disease hospitalized in Imam Khomeini Hospital, distilled water (placebo) was administered by inhalation in the amount of 4cc by Ultrasonic Nebulier CUN60 every 12 hours for 72 hours and a total of 24cc. .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital (RA)
Full name of responsible person
Dr. Akram Sardari
Street address
Imam Khomeini Hospital., Doctor Gharib Street
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2762
Email
sardaricardio@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akram Sardari
Street address
Imam Khomeini Hospital., Doctor Gharib Street
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2762
Email
sardaricardio@gmail.com
Grant name
Research assistant of Tehran University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Kazem Gharloghi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Imam Khomeini Hospital., Doctor Gharib Street
City
Tehran
Province
Tehran
Postal code

1419733141

Phone

+98 21 6119 2762

Email

Dr.K.Gharloghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Sardari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Khomeini Hospital., Doctor Gharib Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2762

Email

sardaricardio@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Sardari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Imam Khomeini Hospital., Doctor Gharib Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2762

Email

sardaricardio@gmail.com

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 data can potentially be shared after de-identifying individuals. The specific title of the documentation is the relationship between inhaled verapamil and pulmonary artery pressure in COPD patients .

When the data will become available and for how long

The access period starts one year after the results are published.

To whom data/document is available

It is possible to access the data for all researchers working in academic and scientific institutions as well as people working in the industry.

Under which criteria data/document could be used

There are no other conditions and restrictions for the use of data.

From where data/document is obtainable

Visiting the library of Imam Khomeini Hospital and the library of the Faculty of Medicine of Tehran University of Medical Sciences. Email address : 1- sardaricardio@gmail.com 2- Dr.K.Gharloghi@gmail.com

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

The applicant can access the data files by providing valid documents for scientific research or industry-related work.

Comments