

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of verapamil nebulizer on oxygenation in COPD patients admitted to ICU

Protocol summary

Study aim

In this study, we have attempted to evaluate the effect of inhaled verapamil on oxygenation in Chronic obstructive pulmonary disease (COPD) patients under intensive care.

Design

Clinical trial with control parallel group, double-blind, randomized with odd and even numbers. The sample size is 40 patients. The implementation phase is 1-2.

Settings and conduct

This study is carried out in the intensive care unit of Dr. Masih Daneshvari Hospital, Tehran. The amount of 10 mg of verapamil was administered as an inhaler to patients who had entered the design, and normal saline nebuliser was administered to patients who had entry criteria and in the placebo group. Except for the ICU resident physician, other elements of the plan include patients, those who collected the information, and the person analyzing the information are not aware of the groupings.

Participants/Inclusion and exclusion criteria

All ICU-admitted COPD patients of Masih Daneshvari Hospital, Tehran were collected those with ● Bradycardia ● Atrioventricular Block ● Cardiac muscle weakness due to amiodarone and other calcium blockers ● Concomitant use of digoxin ● Taking phenobarbital and phenytoin drugs ● Co-administration of β -adrenergic receptors blockers ● Patients with QT disorders were excluded from the study.

Intervention groups

1. Verapamil 2- Placebo

Main outcome variables

Primary Outcomes: - Arterial oxygen saturation - Score of patients' shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170210032478N1**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **retrospective**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2163

Email address

dr.f.ghorbani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-31, 1397/03/10

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

2017-11-22, 1396/09/01

Actual recruitment end date

2018-04-09, 1397/01/20

Trial completion date

empty

Scientific title

The effect of verapamil nebulizer on oxygenation in COPD patients admitted to ICU

Public title

Verapamil effect on COPD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All ICU- admitted COPD patients

Exclusion criteria:

pregnancy sever hepato renal dysfunction AV block or arrhythmia EF less than 40% verapamil hypersensitivity beta-adrenergic receptor drugs QT disorders in patients Bradycardia co- administration of Digoxin

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using even and odd numbers , the patients are simply randomized and placed in two groups of intervention and placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to treat any possible complications, the physician who provide clinical care, is not blind. Other blind groups are as below: Participants Principal investigator Data collection authorities Outcome manager

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of National Research Institute of Tuberculosis and Lung Diseases

Street address

Niavaran, Daaraabaad

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Postal code

1956744413

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.sbm.nritld.rec.1397.513

Health conditions studied**1****Description of health condition studied**

Chronic obstructive pulmonary disease

ICD-10 code

J00-J99

ICD-10 code description

Diseases of the respiratory system

Primary outcomes**1****Description**

Arterial Oxygenation Blood gaz

Timepoint

20 minutes after taking the medication or placebo for 3 days, Q 12 h

Method of measurement

Arterial Blood Gaz

2**Description**

BORG scale

Timepoint

20 minutes after taking the medication or placebo for 3 days, Q 12 h

Method of measurement

Tacking History

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Inhalation of Verapamil

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center
Masih Daneshvari Hospital

Full name of responsible person

Giti Pourdoulat

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Web page address<http://www.nritld.sbm.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

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Grant name

14200

Grant code / Reference number

14200

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

National Research Institute of Tuberculosis and Lung Diseases

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**

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Fariba Ghorbani

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Giti Pourdoulat

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact**

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Full name of responsible person

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Associate professor

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable