

# 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  $\beta$ -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

##### City

Tehran

## Province

Tehran

## Postal code

1956744413

## Approval date

2018-05-29, 1397/03/08

## Ethics committee reference number

IR.sbm.u.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

**Street address**

Daaraabaad, Niavaran

**City**

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**Postal code**

1956944413

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**Email**

dr.f.ghorbani@sbm.ac.ir

**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**

Dr. Parisa Farnia

**Street address**

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**Email**

tdrc.nritld@yahoo.com

**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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**Web page address**<http://www.nritld.sbm.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

National Research Institute of Tuberculosis and Lung Diseases

**Full name of responsible person**

Giti Pourdoulat

**Position**

Assistant Professore

**Latest degree**

Subspecialist

**Other areas of specialty/work**

pulmonology

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**Person responsible for updating data****Contact**

**Name of organization / entity**

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Behrooz Frzanegan

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Intensivist

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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