

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation efficacy of Tadalafil and Bosentan on pulmonary arterial pressure, cardiac output and prognosis of mechanical ventilation in COPD patients with pulmonary hypertension under mechanical ventilation

#### Protocol summary

##### Study aim

Evaluation efficacy of Tadalafil and Bosentan on pulmonary arterial pressure, cardiac output and prognosis of mechanical ventilation in COPD patients with pulmonary hypertension under mechanical ventilation

##### Design

This study is a randomized clinical trial with parallel groups without blinding and phase 2-3. Patients admitted to the intensive care unit after random allocation will be divided into two groups

##### Settings and conduct

In this study, which will be performed in the intensive care unit of Imam Reza Hospital (Tabriz), 100 patients will be included in the study and will receive the intervention after random allocation. Bosentan will be given 125 mg twice daily and Bosentan 40 mg once daily, and finally lung tests will be measured and compared.

##### Participants/Inclusion and exclusion criteria

After entering the study, patients will be divided into two groups: Bosentan and Tadalafil using a random number table. Randomization list by assigning B and T codes to the two groups of Bosentan tablets (twice daily) and Tadalafil tablets (once daily) and with the help of the website <https://www.sealedenvelope.com/simple-randomiser/v1/> lists will be done.

##### Intervention groups

After randomly assigning patients to two groups, Bosentan will be given 125 mg twice daily for the bosentan group and 40 mg once daily for the tadalafil group; Before and after the intervention, the impact volume, left ventricular and pulmonary artery pressure will be measured and compared.

##### Main outcome variables

Pulmonary function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N24**

Registration date: **2021-10-14, 1400/07/22**

Registration timing: **prospective**

Last update: **2021-10-14, 1400/07/22**

Update count: **0**

##### Registration date

2021-10-14, 1400/07/22

##### Registrant information

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-21, 1400/08/30

##### Expected recruitment end date

2022-03-16, 1400/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation efficacy of Tadalafil and Bosentan on pulmonary arterial pressure, cardiac output and prognosis of mechanical ventilation in COPD patients with pulmonary hypertension under mechanical ventilation

## Public title

Tadalafil and Bosentan on pulmonary arterial pressure, cardiac output and prognosis of mechanical ventilation in COPD patients with pulmonary hypertension under mechanical ventilation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

History of COPD Hospitalized in the pulmonary intensive care unit Under controlled breathing or connected to a ventilator

### Exclusion criteria:

Body mass index higher than 30 Lung cancer and any other type of cancer Right and left ventricular dysfunction Chest radiotherapy during the last month

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After entering the study, patients will be divided into two groups: Bosentan and Tadalafil using a random number table. Randomization list by assigning B and T codes to the two groups of Bosentan tablets (twice daily) and Tadalafil tablets (once daily) and with the help of the website

<https://www.sealedenvelope.com/simple-randomiser/v1/> lists will be done.

## 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 Tabriz University of Medical Sciences

## Street address

Tabriz University of Medical Sciences, Azadi Ave

## City

Tabriz

## Province

East Azarbaijan

## Postal code

5165665631

## Approval date

2020-06-08, 1399/03/19

## Ethics committee reference number

IR.TBZMED.REC.1399.261

## Health conditions studied

### 1

#### Description of health condition studied

Chronic obstructive pulmonary disease

#### ICD-10 code

J44.9

#### ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

## Primary outcomes

### 1

#### Description

Pulmonary function

#### Timepoint

Once every three days for three weeks

#### Method of measurement

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients will be treated with the available drugs for three weeks, so that patients in the Bosentan group will receive 125 mg of the drug twice a day.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: For patients in the tadalafil group, this drug will be given at a dose of 40 mg once a day.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Khalil Ansarin

**Street address**

Imam Reza Hospital, Azadi Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

6165665631

**Phone**

+98 41 3335 5921

**Email**

Dransarin@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

**Street address**

Imam Reza Hospital, Azadi Ave

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+98 41 3335 7310

**Email**

Ajouyban@hotmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohsen Pishbin

**Position**

Doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Reza Hospital, Azadi Ave

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**Province**

East Azarbaijan

**Postal code**

5981764863

**Phone**

+98 41 3334 7054

**Fax****Email**

Pishbin@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Khanbabayi Gol

**Position**

MSc in Nursing Education

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**City**

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**Phone**

+98 41 3334 7054

**Fax****Email**

Khanbabayimehdi69@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Khanbabayi Gol

**Position**

MSc in Nursing Education

**Latest degree**

Master

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**Fax****Email**

Khanbabayimehdi69@gmail.com

**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**

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**

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