

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

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Dransarin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Position

MSc in Nursing Education

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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

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