Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

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

Protocol summary

Study aim
Evaluation efficacy of Tadalafil and Bosentan on pulmonary arterial pressure, cardiac outupt and prognosis of mechanical ventilation in COPD patients with pulmonary hypertenion 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 Bosadant 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 Tadalfil using a random number table. Randomization list by assigning B and T codes to the two groups of Bosentan tablets (twice daily) and Tadalfil 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 tadalfil 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 outupt and prognosis of mechanical ventilation in COPD patients with pulmonary hypertenion under mechanical ventilation

Public title
Tadalafil and Bosentan on pulmonary arterial pressure, cardiac outupt and prognosis of mechanical ventilation in COPD patients with pulmonary hypertenion 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 Tadalfil using a random number table. Randomization list by assigning B and T codes to the two groups of Bosentan tablets (twice daily) and Tadalfil 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
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Phone
+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
City
Tabriz
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
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
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
Other areas of specialty/work
Nursery
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 3334 7054
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