Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Comparison assessment of Bosentan and routine medication on pulmonary hypertension among hospitalized patients with COVID-19

Protocol summary

Study aim

Evaluation of the effect of Bosentan in the treatment of pulmonary pressure in patients with COVID-19 in Bu Ali Sina Hospital in Qazvin in 2021

Design

A double-blind randomized clinical trial study with a control group with a parallel design; on 60 patients. Block randomization method was used for randomization.

Settings and conduct

The study population is patients with COVID-19 admitted to Bouali sina Hospital in Qazvin in 2021 who has developed COVID-19 pneumonia and pulmonary hypertension. Blinding in this study is double blind that the drug and placebo are labeled by the manufacturer as "Group A" and "Group B". They are quite similar in appearance and the person participating in the study and the person distributing the medicine does not know about this labeling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19 referred to Bouali Hospital, Qazvin, in 2021, Patients with COVID-19 pneumonia and pulmonary hypertension Exclusion criteria: age under 14 years, pregnant women, history of pulmonary hypertension, no severe obstructive pulmonary disease.

Intervention groups

The intervention group is patients with COVID-19 with pulmonary pressure that receive Bosentan 62.5mg twice a day for 10 days in addition to the drugs used in the treatment of COVID-19 (approved by the National Committee). The control group is patients with COVID-19 with pulmonary pressure that receive only the drugs used in the treatment of COVID-19 (approved by the National Committee).

Main outcome variables

Pulmonary artery systolic pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210710051831N1**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **prospective**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Fahimeh Shokrollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3378 5097

Email address

fahimeshokrollahi@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-23, 1400/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison assessment of Bosentan and routine medication on pulmonary hypertension among hospitalized patients with COVID-19

Public title
The effect of Bosentan in the treatment of pulmonary hypertension in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with COVID-19 referred to Boali Sina hospital, Qazvin during 1400 patients with COVID-19 pneumonia and pulmonary hypertension Willingness to participate in a research project Signing the informed consent form
Exclusion criteria:
Age range under 14 years Pregnant women History of pulmonary hypertension Severe obstructive pulmonary disease
Age
From **15 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sampling is simple in that the names of all patients participating in the project is written and 60 people, which is equivalent to the sample size, will be selected by lot and through Permuted- Block randomization with blocks of size 8 (consisting of 4 participants in the intervention and 4 participants in the control groups) is used for random allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study is double blind that the drug and placebo are labeled by the manufacturer as "Group A" and "Group B". They are quite similar in appearance and the person participating in the study and the person distributing the medicine does not know about this labeling. the drug and placebo were labeled by the manufacturer Group A and Group B. Which are quite similar in appearance and the person participating in the study and the person distributing the medicine does not know about this labeling.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Boali Sina hospital, Boali Ave
City
Qazvin
Province
Qazvin
Postal code
3413786165
Approval date
2021-04-19, 1400/01/30
Ethics committee reference number
IR.QUMS.REC.1400.026

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

2

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Pulmonary artery systolic pressure
Timepoint
Before and 10 days after the intervention
Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The case group in addition to the drugs used in the treatment of COVID-19 (approved by the National Committee), is treated with Bosentan 62.5mg twice a day for 10 days.
Category
Treatment - Drugs

2

Description
Control group: Patients receive only the drugs used to treat COVID-19 (approved by the National Committee).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali Sina Hospital
Full name of responsible person
Fahimeh Shokrollahi
Street address
Boali Sina Hospital, Boali Sina Ave
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fahimeshorollahi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad mahdi Emamjomeh
Street address
Vice Chancellor of Research and Technology, Valiasr Street
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3415613911
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+98 28 3333 7006
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memamjomeh@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Fahimeh Shokrollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable