

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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@gmail.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

City

Qazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 2930

Email

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

City

Qazvin

Province

Qazvin

Postal code

3415613911

Phone

+98 28 3333 7006

Email

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

Street address

Boali Sina Hospital, Boali Sina Ave

City

Qazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 2930

Email

fahimeshorollahi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Fahimeh Shokrollahi

Position

Reident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Boali Sina Hospital, Boali Sina Ave
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3333 2930
Email
fahimeshorollahi@yahoo.com

Person responsible for updating data

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
Street address
Boali Sina Hospital, Boali Sina Ave
City

Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3333 2930
Email
fahimeshokrollahi@ymail.com

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