

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

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Boali Sina Hospital, Boali Sina Ave

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

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##### Position

Reident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

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## 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**  
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Qazvin  
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**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