

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effect of bosentan with routine protocol on clinical outcomes of hospitalized patients with COVID-19 infection.

Protocol summary

Study aim

Determining the effect of bosentan on clinical outcomes of hospitalized patients with COVID-19 infection in comparison with routine protocol

Design

Double-blind randomized controlled clinical trial

Settings and conduct

In this study, COVID-19 patients, hospitalized in Shahid Mostafa Khomeini and Imam Khomeini hospitals with the mentioned inclusion and exclusion criteria will be studied. Bosentan and placebo tablets are similar, and patients and researchers are unaware of labeling. Bosentan 62.5 mg tablets will be given twice daily. Patients are followed up daily. After discharge, they will be followed up for 30 days from the time of intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Written informed consent; Age over 18 years; Laboratory-confirmed SARS-CoV-2 infection; Exclusion Criteria: • Pregnancy; Lactation; Glibenclamide Consumption; Cyclosporine Consumption; Aminotransferases > 3 times normal; Allergy to bosentan

Intervention groups

Oral Bosentan 62.5 mg, twice daily, for 30 days.

Main outcome variables

The time to clinical improvement, defined as the time from randomization to an improvement of two points (from the status at randomization) on a WHO 11 point clinical progression scale or live discharge from the hospital, whichever came first.

General information

Reason for update

Start recruitment process

Acronym

IRCT registration information

IRCT registration number: **IRCT20211203053263N2**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **prospective**

Last update: **2022-07-19, 1401/04/28**

Update count: **2**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Shaahin Shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 3960

Email address

mdkabe@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-27, 1400/12/08

Expected recruitment end date

2022-05-29, 1401/03/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of bosentan with routine protocol on clinical outcomes of hospitalized patients with COVID-19 infection.

Public title

Bosentan in hospitalized patients with COVID-19 infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written informed consent prior to initiation of study. Age over 18 years. Laboratory-confirmed SARS-CoV-2 infection determined by PCR less than 72 hours before randomization. Illness of any duration, and at least one of the following: Radiographic infiltrates by imaging , OR Clinical assessment (evidence of rales/crackles on exam) AND SpO2 $\leq$ 94% on room air, OR Requiring mechanical ventilation and/or supplemental oxygen. Women of childbearing potential must agree to use at least one primary form of contraception for the duration of the study.

Exclusion criteria:

Pregnancy or Lactation
Glibenclamide Consumption
Cyclosporine Consumption
Aminotransferases > 3 times normal
Allergy to bosentan

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization will be used for random allocation. The size of the blocks will randomly selected. There are 4, random blocks, each has an equal number of interventions and controls. In the 4 blocks, two allocations are considered for the intervention group and two allocations for the control group. Random Allocation Software will be used for this purpose. The concealment will be done using sequentially numbered, sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding in this study is double blind that the drug and placebo are labeled 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.

Placebo

Used

Assignment

Parallel

Other design features

This study is an adaptive and add on trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Ilam University of Medical Sciences

Street address

Banghanjab Blv.

City

Ilam

Province

Ilam

Postal code

1639393939

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.MEDILAM.REC.1400.220

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

The time to clinical improvement, defined as the time from randomization to an improvement of two points (from the status at randomization) on a WHO 11 point clinical progression scale or live discharge from the hospital, whichever came first.

Timepoint

During hospitalization

Method of measurement

WHO 11 point clinical progression scale

Secondary outcomes

1

Description

Proportion of patients in each category of the WHO 11 point clinical progression scale on day 30 after randomization

Timepoint

Day 30

Method of measurement

WHO 11 point clinical progression scale

2

Description

Duration of mechanical ventilation

Timepoint

During hospitalization

Method of measurement

Mechanical ventilation, Observation

3

Description

Duration of hospitalization in survivors

Timepoint

During intervention

Method of measurement

Observation, Medical report

4

Description

The composite of symptomatic deep venous thrombosis; pulmonary embolism; arterial thromboembolism; myocardial infarction; ischemic stroke, up to 30 days after treatment initiation

Timepoint

30 days from intervention

Method of measurement

Observation

5

Description

30 days mortality

Timepoint

30 days from intervention

Method of measurement

Observation, Medical report

6

Description

Sarcopenia

Timepoint

Change from baseline at 3-12 months

Method of measurement

EWGSOP2 criteria

7

Description

Functional status

Timepoint

Change from baseline at 3-12 months

Method of measurement

Post-Covid Functional Scale

8

Description

dyspnea

Timepoint

Change from baseline at 3-12 months

Method of measurement

MMRC dyspnea scale

9

Description

fatigability

Timepoint

Change from baseline at 3-12 months

Method of measurement

chalder fatigue scale

10

Description

Sleep disorders

Timepoint

Change from baseline at 3-12 months

Method of measurement

Pittsburgh Sleep Questionnaire

11

Description

Brain fog

Timepoint

Change from baseline at 3-12 months

Method of measurement

Visual Analog Scale

12

Description

Loss of taste and smell

Timepoint

Change from baseline at 3-12 months

Method of measurement

Visual Analog Scale

13

Description

thromboembolic events

Timepoint

Change from baseline at 3-12 months

Method of measurement

clinical and paraclinical exam

14

Description

Changes in serum level of CMP

Timepoint

Change from baseline at 3-12 months

Method of measurement

Serum measurement

15

Description

Change in Weight

Timepoint

Change from baseline at 3-12 months

Method of measurement

Weight scale

16

Description

Changes in Subject's quality of life

Timepoint

Change from baseline at 3-12 months

Method of measurement

Health Survey Questionnaire

17

Description

Assessment of sexual function

Timepoint

Change from baseline at 3-12 months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: The study group in addition to the drugs used in the treatment of COVID-19 (approved by the National Committee), is treated with oral Bosentan 62.5 mg twice a day for 30 days. Patients will be followed for 30 days for recovery or discharge, duration of mechanical ventilation dependency, length of hospital stay, mortality, and thromboembolic events.

Category

Treatment - Drugs

2

Description

Control group: The control group, in addition to the drugs used in the treatment of COVID-19 (approved by the National Committee), receive a placebo twice a day for 30 days. Patients will be followed for 30 days for recovery or discharge, duration of mechanical ventilation dependency, length of hospital stay, mortality, and thromboembolic events.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomainsi hospital of Ilam

Full name of responsible person

Shaahin Shahbazi

Street address

Tapeh Khargooshan St

City

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Province

Ilam

Postal code

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Phone

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Email

mdkabe@gmail.com

Web page address

<http://mostafahospital.medilam.ac.ir>

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ilam

Full name of responsible person

Shaahin Shahbazi

Street address

Heidari street.

City

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Province

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Postal code

6931975397

Phone

+98 84 3333 4500

Email

mdkabe@gmail.com

Web page address

<http://emamhospital.medilam.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Shaahin Shahbazi

Street address

Banghanjab Blv.

City

Ilam

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Ilam

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Phone

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Email

mdkabe@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Ilam University of Medical Sciences
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Shaahin Shahbazi
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Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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