

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of Bosentan with routine protocol on outcomes of high-risk outpatients with COVID-19 infection.

Protocol summary

Study aim

Assessment of effects of Bosentan therapy on outcomes of outpatients with COVID-19

Design

A double-blind randomized adaptive clinical trial study with a control group with a parallel design; on 300 patients. Block randomization method will be used for randomization.

Settings and conduct

This study will enroll adults presenting to the the clinic of Mostafa Khomainsi hospital with mild, laboratory-confirmed COVID-19 illness, who are at high risk for progression to severe/critical illness, but who are clinically stable for outpatient management. 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: One or more symptoms of COVID-19 illness and laboratory-confirmed SARS-CoV-2 determined by PCR assay < 72 hours prior to randomization, Has at least one CDC defined risk factor for severe COVID-19 illness, Clinical team deems stable for outpatient management without supplemental oxygen, Has informed consent women of child bearing 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 level> 3 times normal, Allergy to bosentan

Intervention groups

The study group will receive tab Bosentan 62.5 mg twice daily and the control group will receive placebo.

Main outcome variables

Disease progression defined as death or hospital admission or seeking emergency or urgent care within 15 days

General information

Reason for update

To update sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20211203053263N1**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-29, 1402/02/09**

Update count: **5**

Registration date

2021-12-15, 1400/09/24

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

2021-12-15, 1400/09/24

Expected recruitment end date

2023-03-15, 1401/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Bosentan with routine protocol on outcomes of high-risk outpatients with COVID-19 infection.

Public title

Bosentan for high-risk outpatients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

One or more symptoms of COVID-19 illness and laboratory-confirmed SARS-CoV-2 determined by PCR assay < 72 hours prior to randomization Has at least one CDC defined risk factor for severe COVID-19 illness Clinical team deems stable for outpatient management without supplemental oxygen Has informed consent women of child bearing 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: **350**

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 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 add on trial study

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

2021-12-15, 1400/09/24

Ethics committee reference number

IR.MEDILAM.REC.1400.164

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

Disease progression within 15 days after randomization is defined as death or hospitalization.

Timepoint

During within 15 days after intervention

Method of measurement

clinical and paraclinical data

Secondary outcomes

1

Description

Thromboembolic events

Timepoint

within 30 days after intervention

Method of measurement

clinical and paraclinical data

2

Description

Death from any cause

Timepoint

within 30 days after intervention

Method of measurement

Patient's medical record

3

Description

Sarcopenia

Timepoint

Change from baseline at 1-12 months

Method of measurement

AWGS criteria

4

Description

Functional status

Timepoint

Change from baseline at 1-12 months

Method of measurement

Post-Covid Functional Scale

5

Description

dyspnea

Timepoint

Change from baseline at 1-12 months

Method of measurement

MMRC dyspnea scale

6

Description

fatigability

Timepoint

Change from baseline at 3-12 months

Method of measurement

chalder fatigue scale

7

Description

Sleep disorders

Timepoint

Change from baseline at 1-12 months

Method of measurement

Pittsburgh Sleep Questionnaire

8

Description

Brain fog

Timepoint

Change from baseline at 1-12 months

Method of measurement

Visual Analog Scale

9

Description

Loss of taste and smell

Timepoint

Change from baseline at 1-12 months

Method of measurement

clinical and paraclinical exam

10

Description

Change in Weight

Timepoint

Change from baseline at 1-12 months

Method of measurement

Weight scale

11

Description

Changes in Subject's quality of life

Timepoint

Change from baseline at 1-12 months

Method of measurement

Health Survey Questionnaire

12

Description

Assessment of sexual function

Timepoint

Change from baseline at 1-12 months

Method of measurement

questionnaire

13

Description

Food Intake assessment

Timepoint

Change from baseline at 1-12 months

Method of measurement

questionnaire

14

Description

Hospital-free days

Timepoint

within 30 days after randomization

Method of measurement

Medical record

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 oral Bosentan 62.5 mg twice a day for 30 days.

Category

Treatment - Drugs

2**Description**

Control group: 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**

Ilam Mostafa Khomaini hospital

Full name of responsible person

Shaahin Shahbazi

Street address

Tapeh Khargooshan St

City

Ilam

Province

Ilam

Postal code

1639393939

Phone

+98 84 3333 8228

Email

mdkabe@gmail.com

Web page address<http://mostafahospital.medilam.ac.ir/>**2****Recruitment center****Name of recruitment center**

Ilam Imam Khomeiny hospital

Full name of responsible person

Shaahin Shahbazi

Street address

Heidari street , Emamkhomeini hospital

City

Ilam

Province

Ilam

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

Province

Ilam

Postal code

1639393939

Phone

+98 84 3333 8228

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

Shaahin Shahbazi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

Street address

Banghanjab Blv.

City

Ilam

Province

Ilam

Postal code

1639393939

Phone

+98 84 3333 8228

Email

mdkabe@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Shaahin Shahbazi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

Street address

Banghanjab Blv.

City

Ilam

Province

Ilam

Postal code

1639393939

Phone

+98 84 3333 8228

Email

mdkabe@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Shaahin Shahbazi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology

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Ilam

Province

Ilam

Postal code

1639393939

Phone

+98 84 3333 8228

Email

mdkabe@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

Not applicable

Data Dictionary

Not applicable