Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 Khomaini 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 recieve 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 Emam 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
Street address
Banghanjab Blv.
City
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