

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation of the efficacy and safety of Co-trimoxazole in patients with COVID-19: A randomized open-label clinical trial

Protocol summary

Study aim

Efficacy and safety of Co-trimoxazole in patients with COVID-19

Design

Clinical trial of the effectiveness of Co-trimoxazole on COVID-19 patients with control and intervention groups, with parallel groups, randomized by simple randomization, 60 patients in two groups of intervention (30) and control (30).

Settings and conduct

The study is performed on patients with Covid_19 in the medical, educational and research complex of the Great Prophet in Bandar Abbas, and patients are in two groups of intervention and control, which are randomized and we will not have blindness.

Participants/Inclusion and exclusion criteria

Inclusion requirements: Age 18 or older, informed and voluntary consent, definitive diagnosis of COVID-19 by PCR test, early signs of moderate-severity disease admitted to hospital Exclusion criteria: multiple organ failure, severe ARDS, septic shock, severe liver disease, acute kidney damage (where GFR is <15), drug sensitivity/intolerance to co-trimoxazole/sensitivity to drugs with sulfur structure, women during pregnancy and lactation and taking other antiviral drugs, tocilizumab or plasma therapy.

Intervention groups

The intervention group consists of patients who will receive Co-trimoxazole along with standard treatment, and Co-trimoxazole will be administered twice a day for 7 days at a dose of 960 mg (2 tablets 480 mg). The control group includes patients who will receive only standard treatment according to the Protocol of the Ministry of Health and Medical Education including remdesivir and Interferon Beta-1a.

Main outcome variables

Initial: Reduction of viral load in PCR test at the end of the study (seventh day or discharge time), improvement of clinical symptoms during the intervention period

Secondary: Length of hospital stay, need for intensive care unit and improvement of biochemical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220407054446N1**

Registration date: **2022-05-22, 1401/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

Registration date

2022-05-22, 1401/03/01

Registrant information

Name

Maryam Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 918 553 7450

Email address

mbabae324@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Co-trimoxazole in patients with COVID-19: A randomized open-label clinical trial

Public title

Evaluation of the efficacy and safety of Co-trimoxazole in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years or older Conscious and voluntary satisfaction Definitive diagnosis of COVID-19 disease by PCR test Hospitalized with early sign of moderate disease

Exclusion criteria:

Multiple organ failure Severe ARDS Septic shock Acute kidney injury (which GFR is <15) Drug allergy / Sensitivity to drugs with sulfuric structure / Intolerance to co-trimoxazole Women during pregnancy and lactation, taking other antiviral drugs, tocilizumab or plasma therapy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, the number of people in each study group is equal to each other during treatment. According to the number of 60 participants (30 people in each group) and the approximate time of 10 weeks to complete the entry of people into the study, out of 10 blocks of 6 people (if there is a sufficient number of 5 blocks of 12) will be used. The procedure in this type of randomization is similar to the simple randomization method, only the number of people in the two treatment groups is the same during the treatment period. The only drawback of this method is that the last group in each block is specified.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, SPSS software version 18 is used for statistical analysis. To compare the main efficacy indices (Reduction of viral load of improvement of clinical symptoms) as primary and secondary outcome between

study groups, t-test for continuous quantitative variables or Wilcoxon test (if t test is not used).) Is used for quantitatively discrete ranking variables. Statistical description of qualitative variables will be in frequency or percentage of observation and Chi-square or Fisher's exact tests will be used to compare between groups. For all statistical tests, $P < 0.05$ (two-way) is considered statistically significant.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hormozgan University of Medical Sciences

Street address

Infectious diseases and Tropical Diseases Research Center, After Burn Emergency, Rasoul Akram Educational and Therapeutic Complex, Islamic Republic Boulevard, Bandar Abbas, Iran

City

Bandar Abbas

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Hormozgan

Postal code

33346994-076

Approval date

2022-01-04, 1400/10/14

Ethics committee reference number

IR.HUMS.REC.1400.415

Health conditions studied**1****Description of health condition studied**

Coronavirus disease (COVID-19)

ICD-10 code

U07.1

ICD-10 code description

Severe acute respiratory syndrome [SARS]

Primary outcomes**1****Description**

Reduction of viral load at the end of the study

Timepoint

At the end of the seventh day or discharge time

Method of measurement

PCR(Polymerase Chain Reaction) test

2**Description**

Improvement of clinical symptoms during the intervention period (improvement of clinical symptoms as continuous improvement (more than 72 hours)

Timepoint

Daily follow up and repeated measurements are performed at least twice per follow up.

Method of measurement

Oral temperature ≥ 36.6 °C; respiratory frequency ≥ 24 times per minute; and oxygen saturation $\leq 98\%$ without mechanical respiration. In addition, the need for oxygen therapy and ventilation with non-invasive positive pressure in daily follow up along with other clinical symptoms such as cough, muscle pain, headache, shortness of breath, weakness and lethargy, decreased sense of smell and taste, diarrhea, abdominal spasm, nausea and vomiting are recorded qualitatively.

Secondary outcomes

1

Description

Length of hospital stay

Timepoint

Beginning of study and end of study (day 7 of study or discharge time)

Method of measurement

CBC tests, subtraction count of white cells, ferritin, CRP, LDH, ESR, creatinine and serum nitrogen urea

2

Description

Need to be admitted to the intensive care unit

Timepoint

Beginning of study and end of study (day 7 of study or discharge time)

Method of measurement

CBC tests, subtraction count of white cells, ferritin, CRP, LDH, ESR, creatinine and serum nitrogen urea

3

Description

Improvement of biochemical parameters of patients

Timepoint

Beginning of study and end of study (day 7 of study or discharge time)

Method of measurement

CBC tests, subtraction count of white cells, ferritin, CRP, LDH, ESR, creatinine and serum nitrogen urea

4

Description

Side effects of the drugs studied

Timepoint

Side effects are recorded daily in the studied groups.

Method of measurement

Side effects of the studied drugs, especially those such as hypersensitivity reactions, allergies, doubts, anemia, hypotension, nausea and vomiting, diarrhea, gastrointestinal spasms, weakness and lethargy,

headache, and rash), frequency of possible side effects due to intervention and frequency of withdrawal due to side effects are recorded daily in the studied groups.

Intervention groups

1

Description

Intervention group: Co-trimoxazole, along with standard treatment, will be administered at a dose of 960 mg (2 tablets of 480 mg) twice a day for 7 days.

Category

Treatment - Drugs

2

Description

Control group: Include patients who will receive only standard treatment in accordance with the Protocol of the Ministry of Health and Medical Education, including remdesivir and Interferon Beta-1a.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Great Prophet Research and Educational Complex Research Center

Full name of responsible person

Dr. Elham Barahimi GhaleGhazi

Street address

The Great Prophet Research and Educational Complex Research Center, Shahid Mohammadi Hospital, Jomhory Blvd, Old Airport, Bandar Abbas, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Elham Barahimi

Street address

Vice Chancellor Deputy of research and technology , Campus of University of Medical Sciences behind the

Central Library, Nabout Town, in front of Kargaran Sports Club, at the beginning of Imam Hossein Boulevard, Bandar Abbas, Iran

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research@hums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Sahar Defaei

Position

Lung physician and faculty member of Hormozgan University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Elham Barahimi GhaleGhazi

Position

Infectious disease specialist

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Sahar Defaei

Position

Lung specialist and faculty member of Hormozgan University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be collected by the colleagues participating in the project

When the data will become available and for how**long**

two months

To whom data/document is available

Corresponding Author: Dr. Elham Barahimi GhaleGhazi ,
Dr. Sahar Defaei, Dr. Mehdi Hassani Azad, Dr.
Mohammad Fath Alipour

Under which criteria data/document could be used

Only for data collection and analysis

From where data/document is obtainable

Dr. Sahar Defaei

What processes are involved for a request to access data/document

Written request and request of the project manager and main collaborators (Dr. Sahar Defaei, Dr. Elham Brahimi, Dr. Mehdi Hassani Azad)

Comments