Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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
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Iran (Islamic Republic of)
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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
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Bandar Abbas
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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 ≤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
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Full name of responsible person
Dr. Elham Barahimi GhaleGhazi

Position
Infectious disease specialist

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Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

Contact

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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

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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