Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

An international randomised trial of additional treatments (Arttesunate, Infliximab, Imatinib) for COVID-19 in hospitalised patients who are all receiving the local standard of care

Protocol summary

Study aim

Efficacy of additional treatments (Infliximab, Imatinib) in hospitalized covid-19 patients

Design

In parallel randomized clinical trial, information of hospitalized patients with covid-19 will be gathered electronically immediately before randomization in a web- based data-base (https://data.castoredc.com). Eligible patients will be randomized using a central web-based service. Patients will be randomized between Standard of Care and other treatment options. Prescribing the drug and follow up until discharge or death is done by physician.

Settings and conduct

This trial is done in seven hospitals: Taleghani Hospital, Masih Daneshvari Hospital, Loghman Hospital, and Imam Hossein in Tehran; Razi Hospital in Rasht, Vali-Asr Hospital in Zanjan, and Shahid Beheshti Hospital in Kashan In each hospital, at least one main researcher (PI), and one randomizer are educated to implement the study. Patients are randomized through the Central Web-Base service. Blindness does not take place. When patients die or are discharged, follow-up ceases and their outcome is reported, regardless of whether the trial treatment actually got given.

Participants/Inclusion and exclusion criteria

Hospitalized patients with laboratory-confirmed COVID-19; Adults (age ≥18 years); Not expected to be transferred within 72 hours; In the view of their doctors, no contra-indication to any potentially relevant study drug;

Intervention groups

• Group 1: local standard of care + Infliximab (5 mg/kg/dose (once only), single IV infusion over 2 hours) • Group 2: local standard of care + Imatinib (400 mg/dose; orally once daily; duration of treatment 14 days) • Group 3: local standard of care

Main outcome variables

In-hospital mortality from any cause; Initiation of ventilation; Duration of hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211221053470N1**
Registration date: **2022-01-11, 1400/10/21**
Registration timing: **prospective**

Last update: **2022-01-11, 1400/10/21**
Update count: **0**

Registration date

2022-01-11, 1400/10/21

Registrant information

Name

Hamid Mohaghegh Shalmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2515

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hamidmohaghegh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
An international randomised trial of additional treatments (Arttesunate, Infliximab, Imatinib) for COVID-19 in hospitalised patients who are all receiving the local standard of care

Public title
WHO Solidarity Plus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized patients with laboratory-confirmed COVID-19 Adults (age ≥18 years(Not expected to be transferred within 72 hours
Exclusion criteria:
In the view of their doctors, no contraindication to use relevant drugs No evidence of pregnancy or hepatic disease in imatinib group No evidence of heart failure, TB or liver disease in Infliximab group
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **1000**
Randomization (investigator's opinion)
Randomized
Randomization description
The WHO Solidarity PLUS Trial in Iran will initially evaluate two treatment arms: infliximab and imatinib, in addition to the local standard of care. These drugs were chosen after careful consideration of potential drugs by an independent panel of experts. Based on available data, these drugs were selected for their potential to reduce mortality. Once electronic data collection has been completed the patient automatically enters the trial and a random allocation of their trial treatment is generated (by an algorithm that ensures eventual balance in the characteristics just recorded between each study drug and its controls) and displayed. The patients will be randomly allocated either to local Standard of Care alone or to local Standard of Care plus one of the study drugs: Group 1: local standard of care + Infliximab (5 mg/kg/dose (once only), single IV infusion over 2 hours) • Group 2: local standard of care + Imatinib (400 mg/dose; orally once daily; duration of treatment 14 days) • Group 3: local standard of care
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iranian National Research Ethics Committee
Street address
loor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town
City
Tehran
Province
Tehran
Postal code
1419943471
Approval date
2021-11-28, 1400/09/07
Ethics committee reference number
IR.NREC.1400.012

Health conditions studied

1

Description of health condition studied
covid-19
ICD-10 code
U07.1
ICD-10 code description
covid-19

Primary outcomes

1

Description
In-hospital death from any causes
Timepoint
At the end of study
Method of measurement
Physician report

Secondary outcomes

1

Description
In-hospital mortality subdivided by initial respiratory support
Timepoint
At the end of study

Method of measurement
Physician report

2

Description
Initiation of ventilation (time to first ventilation) in lower-risk patients
Timepoint
During study
Method of measurement
Physician report

3

Description
Duration of hospital stay in lower-risk patients and in higher-risk patients
Timepoint
At the end of study
Method of measurement
Physician report

4

Description
SAEs (serious adverse events) or SUSARs (suspected unexpected serious adverse reaction) possibly related to treatment
Timepoint
During study
Method of measurement
Physician report

Intervention groups

1

Description
Intervention group 1: standard local treatment + infleximab (5mg / kg / dose only single dose as intravenous infusion given to the patient within 2 hours)
Category
Treatment - Drugs

2

Description
Intervention group 2: standard local treatment + imatinib (400 mg / dose orally once daily for 14 days)
Category
Treatment - Drugs

3

Description
Control group: standard local treatment according to national guideline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Afshin Mohammad Alizadeh
Street address
Aerabi Str, Yaman Ave, Evin
City
Tehran
Province
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Postal code
1985711151
Phone
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Email
afshin.alizade@gmail.com

2

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Payam Tabarsi
Street address
Darabad, Bahonar (Niavaran) Str.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
Payamtabarsi@yahoo.com

3

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Hamid Reza Hatamabadi
Street address
Shahid Madani Str., Imam Hossen Sq
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1617763141
Phone
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Email
hhatamabadi@yahoo.com

4

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Ilad, Alavi Darzam
Street address
Kamali Str, Kargar Jonoobi Av.
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5

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
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6

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Maedeh Najafizadeh
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7

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
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Phone
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Fax
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Email
tina.shahani@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
World Health Organization
Full name of responsible person
World Health Organization
Street address
Geneva
City
Geneva
Postal code
1111111111
Phone
+41 22 791 21 11
Email
erecruit@who.int
Web page address
https://www.who.int
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
World Health Organization
Proportion provided by this source
90
Public or private sector
Public
Domestic or foreign origin
Foreign
Category of foreign source of funding
UN agencies and international organizations
Country of origin
Type of organization providing the funding
Other

2

Sponsor

Name of organization / entity
Deputy of Research and Technology, Ministry of Health and Medical Education

Full name of responsible person
Dr. Younes Panahi

Street address
Sima Iran Str., Sharak Ghods

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Tehran

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1419943471

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Email
info@hbi.ir

Grant name

Grant code / Reference number

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

Title of funding source
Deputy of Research and Technology, Ministry of Health and Medical Education

Proportion provided by this source
10

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Alireza Zali

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Evin, Shahid Beheshti University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Research Institute for Gastroenterology and Liver Diseases, SBMU

Full name of responsible person
Hamid Asadzadeh Aghdaie

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
This is a part of an international multi-center study with sponsorship of World Health Organization, and publishing of data should be authorized by WHO.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable