

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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)

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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

AgeFrom **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 + infliximab (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

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2

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Payam Tabarsi

Street address

Darabad, Bahonar (Niavaran) Str.

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Tehran

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1956944413

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Email

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3

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Hamid Reza Hatamabadi

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Shahid Madani Str., Imam Hossein Sq

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4

Recruitment center

Name of recruitment center

Loghman Hospital

Full name of responsible person

Ilad, Alavi Darzam

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Kamali Str, Kargar Jonoobi Av.

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Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Mansour Ghanaie

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Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Maedeh Najafizadeh

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Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

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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

Sponsor**Name of organization / entity**

Deputy of Research and Technology, Ministry of Health and Medical Education

Full name of responsible person

Dr. Younes Panahi

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

Research Institute for Gastroenterology and Liver Diseases, SBMU

Full name of responsible person

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Position

Associate professor

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

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Email

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