

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of clinical course and disease consequences with or without Remdesivir intake in patients with COVID-19 infection

Protocol summary

Study aim

Comparison of clinical symptoms of patients with Covid 19 in the studied groups Comparison of disease severity and status in patients with Covid 19 in the study groups Comparison of clinical improvement and mortality in patients with Covid 19 in the study groups Comparison of oxygen saturation levels and body temperature in patients with Covid 19 in the study groups Comparison of laboratory findings in patients with Covid 19 in each of the studied groups Determining the relationship between disease severity and clinical status in patients receiving Remdesivir with the interval between the onset of symptoms and the start of treatment with Remdesivir

Design

Nonequivalence group devided trial with 100 patients.

Settings and conduct

The study will be performed in Hajar Hospital in Shahrekord and with following and completing a checklist of clinical and laboratory symptoms.

Participants/Inclusion and exclusion criteria

1.patients aged $\geq$ 18 years old 2. SARS-CoV-2 infection confirmed by molecular test and including 1.blood oxygen saturation $\leq$ 93% in room air, or patients in need of supportive oxygen or ventilation or 2.patients with pulmonary infiltration in radiological studies enrolled in the study. Excluding criteria: 1.Alanine aminotransferase and Aspartate aminotransferase rising more than 5 times the upper limit of normal 2.Glomerular filtration rate less than 60ml/minute(according to Cockcroft-Gault formula)

Intervention groups

1. Patients recieving Remdesivir+ standard care 2. Patients recieving standard care

Main outcome variables

Clinical symptoms, laboratory symptoms, mortality rate, hospitalization period, ICU admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210324050760N1**

Registration date: **2021-04-17, 1400/01/28**

Registration timing: **prospective**

Last update: **2021-04-17, 1400/01/28**

Update count: **0**

Registration date

2021-04-17, 1400/01/28

Registrant information

Name

zahra Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

st-rezaei.a@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical course and disease consequences with or without Remdesivir intake in patients with COVID-19 infection

Public title
Effect of Remdesivir in treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Blood oxygen saturation<93% in room air or patients with patients in need of supportive oxygen or ventilation or Patients with pulmonary infiltration in radiological studies
Exclusion criteria:
 Alanine aminotransferase and Aspartate aminotransferase rising more than 5 times the upper limit of normal Glomerular filtration rate less than 30ml/minute(according to Cockcroft-Gault formula)

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
Due to the limit in access to Remdesivir, the study is conducted as a Nonequivalence group. Patients hospitalized in drug availability courses were eligible to receive the drug to comply with ethical principles, and patients admitted in other courses received only standard treatments.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shahrekord University of Medical Sciences.
Street address
 Parastar street
City
 Shahrekord
Province
 Chahar-Mahal-va-Bakhtiari
Postal code

8816754633

Approval date
2021-01-05, 1399/10/16
Ethics committee reference number
 IR.SKUMS.REC.1399.230

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
 mortality or discharge
Timepoint
 End of hospitalization period
Method of measurement
 Patient file

2

Description
 Hospitalization period
Timepoint
 Hospitalization to discharge period
Method of measurement
 Patient file

3

Description
 ICU admission
Timepoint
 From Hospitalization to discharge
Method of measurement
 Patient file

4

Description
 Clinical symptoms
Timepoint
 From hospitalization to discharge
Method of measurement
 Interview and examination

5

Description
 Laboratory data
Timepoint
 From hospitalization to discharge
Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive Remdesivir and standard care. this group will receive 200 mg of Remdesivir IV for first day and 100 mg daily for 4 days plus standard care according to national protocol .

Category

Treatment - Drugs

2

Description

Control group: Patients only receiving standard care according to national protocol with suggested dose and duration and do not receive Remdesivir.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Zahra Rezaei

Street address

Parastar street, Hajar hospital

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rezaeizahra1997@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Mehraban Sadeghi

Street address

Parastar st.

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Ahmad Reisi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Ahmad Reisi

Position

Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Rezaee
Position
Intern
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

2021-2022

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments