Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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≥18 years old 2. SARS-CoV-2 infection confirmed by molecular test and including 1.blood oxygen saturation ≤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. Ẽxcluding 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 Cockroft-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)
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+98 38 3222 0016
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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 Cockroft-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 firs 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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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

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Position

Associate professor

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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