Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment of utility of Remdesivir in Patients with Acute Kidney Injury or Cronic Kidney Disease in admitted COVID-19 patients

Protocol summary

Study aim

Evaluation of the effect of Remdesivir in patients with acute or chronic renal failure with Covid 19

Design

A clinical trial with a control group, parallel groups, one-way blind, randomized, on 100 patients, use the block method (with unequal quadruple sizes) for random allocation.

Settings and conduct

Patients referred to Shohada-e-Tajrish Hospital who were eligible for the study received 200 mg of injectable remdesivir on the first day and then 100 mg every other day. This drug is diluted in 200 cc of normal saline for injection. The control group also received 200 cc of normal saline as a placebo. hepatic and renal complications and function are evaluated and the usefulness of this treatment and recovery is monitored.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute or chronic renal failure with a definitive diagnosis of Covid 19 admitted to the ward ,in the age over 18 years and lung involvement . Exclusion criteria: previous history of COVID-19 and receiving remdesivir, history of lung disease, liver ,Patients admitted in ICU from the beginning, prohibition of remdesivir (except low GFR),Underlying diseases other than renal dysfunction (such as heart failure, active cancer,Advanced diabetes, previous stroke),Immunosuppressive use except in the field of kidney transplantation.

Intervention groups

Patients in the intervention group receive first 200 mg of remdesivir on the first day and then one day between 100 mg Up to 5 doses until the patient recovers or develops complications from remdesivir.The control group receives standard treatment without remdesivir.

Main outcome variables

Duration of hospitalization,Result of hospitalization (death or discharge),Red blood cell count, Platelet count ,White blood cell count, Mean platelet volume,ESR,CRP,AST,ALT,INR,Bilirubin,ALK,Cr,O2 Sat,Lymphocyte cell count,neutrophil count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210709051824N1**
Registration date: **2021-12-08, 1400/09/17**
Registration timing: **prospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **0**

Registration date

2021-12-08, 1400/09/17

Registrant information

Name

mahboobeh freidoon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4443 5377

Email address

m.fereidoon@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of utility of Remdesivir in Patients with Acute Kidney Injury or Cronic Kidney Disease in admitted COVID-19 patients

Public title
Assessment of utility of Remdesivir in Patients with Acute Kidney Injury or Cronic Kidney Disease in admitted COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with acute or chronic renal failure, with a definitive diagnosis of Covid 19, over the age of 18 years, and lung involvement above 20% or hypoxia (oxygen saturation less than or equal to 93%) Definitive diagnosis of Covid 19 Over the age of 18 years Pulmonary involvement caused by Covid 19

Exclusion criteria:
Previous history of COVID-19 infection and heart disease and receiving Remdesivir History of lung disease History of liver disease (such as hepatitis, cirrhosis) History of underlying diseases other than renal impairment that contribute to poor prognosis and increased mortality following coronary heart disease (eg, heart failure, active cancer, advanced diabetes with severe macrovascular and microvascular complications, previous stroke) Immunosuppressive use except in the field of kidney transplantation Prohibition of Ramdesivir (except low GFR)

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocking method (with unequal quadratic sizes) is used for random allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in this study were kept blind (unilaterally blind) after obtaining informed consent to receive the drug or placebo. Medical staff and researchers are aware of this.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs-Shahid Beheshti University of Medi

Street address
Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-09-19, 1400/06/28

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.379

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

2

Description of health condition studied
Acute Kidney Injury

ICD-10 code
N17

ICD-10 code description
Acute kidney failure

3

Description of health condition studied
Chronic Kidney Disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Red blood cell count

Timepoint
The beginning of the visit, While receiving Remdesivir,

after received Remdesivir

Method of measurement

Cell counter

2

Description

Platelet count

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Cell counter

3

Description

White blood cell count

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Cell counter

4

Description

Medium platelet volume

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Cell counter

5

Description

Erythrocyte Sedimentation Rate

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

6

Description

CRP

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

7

Description

AST

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

8

Description

ALT

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

9

Description

International Normalized Ratio(INR)

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

10

Description

Bilirubin

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

11

Description

Alkaline phosphatase

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

12

Description

Cratinin

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

13

Description

O2 Saturation

Timepoint

The beginning of the visit, While receiving Remdesivir, after received Remdesivir

Method of measurement

Laboratory Kit

14

Description

lymphocyte count

Timepoint
The beginning of the visit, While receiving Remdesivir, after received Remdesivir
Method of measurement
Cell counter

15

Description
Neutrophil count
Timepoint
The beginning of the visit, While receiving Remdesivir, after received Remdesivir
Method of measurement
Cell counter

16

Description
Duration of hospitalization
Timepoint
End of hospitalization
Method of measurement
Hospitalization file

17

Description
Result of hospitalization(Death or discharge)
Timepoint
End of hospitalization
Method of measurement
Hospitalization file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group receives 200 mg Remdesivir on the first day as an intravenous infusion and then 100 mg daily up to 5 doses.
Category
Treatment - Drugs

2

Description
Control group: In this group, patients receive placebo with the same dose and number of times as the control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e-tajrish hospital
Full name of responsible person
Mahboobeh Freidoon
Street address
Shohada-e-tajrish hospital, Tajrish Sq.,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
pr-shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Men's Health and Reproductive Health Research Center(MHRHRC)
Full name of responsible person
Seyed Jalil Hoseini
Street address
Tajrish
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 2234
Email
mhrhrc@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Men's Health and Reproductive Health Research Center(MHRHRC)
Proportion provided by this source
20
Public or private sector
Private
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahboobeh Freidoon
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Mahboobeh Freidoon
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Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available