

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

volume,ESR,CRP,AST,ALT,INR,Bilirubin,ALK,Cr,O2 Sat,Lymphocyte cell count,neutrophil count

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

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

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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 Chronic Kidney Disease in admitted COVID-19 patients

Public title

Assessment of utility of Remdesivir in Patients with Acute Kidney Injury or Chronic 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

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Velenjak

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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

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Shohada-e-tajrish hospital, Tajrish Sq.,Tehran, Iran

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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

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Province

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Phone

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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**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahboobeh Freidoon

Position

Assistant Professor

Latest degree

Subspecialist

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Internal Medicine

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

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Position

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Latest degree

Subspecialist

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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