Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the therapeutic effect of Remdesivir on COVID-19 patients, A single-arm clinical trial study

Protocol summary

Study aim
Evaluation of the therapeutic effect of Remdesivir on covid-19 patients referring to Ahvaz Jundishapur University of Medical Sciences hospitals, A single-arm clinical trial study

Design
Single-arm clinical trial study, without control group, with a sample size of 50 people, , Phase 2_3 of Clinical trial

Settings and conduct
The place of the study is Ahvaz University of medical science hospitals, simple sampling of patients without randomization, without blinding, Single-arm clinical trial study, RemedSivir is used

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age ≥18 years, Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19, Severe pulmonary involvement in imaging, Oxygen saturation less than 90% with canola nasal or respiratory rate more than 30. Exclusion criteria: Treatment with other antiviral drugs not listed in the national protocol, Underlying disease, Allergic reaction to Remdesivir, Pregnant or lactating women, Possibility of transfer to another hospital, Evidence of multiple organ failure, Receive any experimental treatment for Covid 19, Patients under mechanical ventilation at the beginning of the study, Alanine Aminotransferase or Aspartate Aminotransferase more than 5 times normal, Creatinine clearance less than 50 ml per minute

Intervention groups
Main group: On the first day of treatment with RamedSivir with two 100 mg vials intravenously for 30 minutes to two hours and then 100 mg daily on the second, third, fourth and fifth days Takes. Each vial is prepared with 19 cc of distilled water and diluted with 0.9% saline.

Main outcome variables
Long of stay, oxygen saturation, fever, dyspnea, cough, Respiratory rate , lymphocyte blood count, C_ reactive protein, Alanine Amino Transferase, Aspartate Aminotransferase

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046937N5**
Registration date: **2020-10-14, 1399/07/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-14, 1399/07/23**
Update count: **0**

Registration date
2020-10-14, 1399/07/23

Registrant information

Name
Mehran Varnaseri ghandali

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3333 7446

Email address
varnaseri-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-27, 1399/07/06

Expected recruitment end date
2020-10-27, 1399/08/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the therapeutic effect of Remdesivir on COVID-19 patients, A single-arm clinical trial study

Public title
Effect of remdesivir in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥18 years Laboratory polymerase chain reaction (PCR) confirmed infection with COVID19 Severe pulmonary involvement in imaging that progresses despite receiving standard treatment protocols within 72 hours of starting antiviral therapy Oxygen saturation less than 90% with canola nasal or respiratory rate more than 30

Exclusion criteria:
Treatment with other antiviral drugs not listed in the national protocol Comorbidities such as malignancy, advanced heart failure, cirrhosis, dialysis patients, stroke, Alzheimer's, advanced neurological disease, progressive respiratory disease Allergic reaction to Remdesivir Pregnant or lactating women Possibility of transfer to another hospital that does not have access to study drugs Evidence of multiple organ failure Receive any experimental treatment for Covid 19 Patients under mechanical ventilation at the beginning of the study Alanine Aminotransferase or Aspartate Aminotransferase more than 5 times normal Creatinine clearance less than 50 ml per minute

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical

Street address
Ethics committee, main building, Ahvaz University of medical science, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6133744151

Approval date
2020-09-22, 1399/07/01

Ethics committee reference number
IR.AJUMS.REC.1399.407

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
Corona virus infection, unspecified

Primary outcomes

1

Description
Length of stay

Timepoint
The first day and the last day of the patient's hospitalization

Method of measurement
patient file

2

Description
Oxygen Saturation

Timepoint
Daily

Method of measurement
Pulls oximeter

Secondary outcomes

1

Description
Fever

Timepoint
Daily

Method of measurement
Thermometer

2

Description
Dyspnea
Timepoint
Daily
Method of measurement
Patients interview and patient file

3

Description
Cough
Timepoint
Daily
Method of measurement
Patients interview and patient file

4

Description
Respiratory Rate
Timepoint
Daily
Method of measurement
Patients interview and patient file

5

Description
C-Reactive protein
Timepoint
The first day and the seventh day of study
Method of measurement
Agglutination kit

6

Description
Lymphocyte blood count
Timepoint
The first day and the seventh day of study
Method of measurement
Cell counter

7

Description
Alanine Amino Transferase
Timepoint
The first day and the seventh day of study
Method of measurement
Determination of enzyme in serum by biochemical method

8

Description
Aspartate Aminotransferase
Timepoint
The first day and the seventh day of study
Method of measurement
Determination of enzyme in serum by biochemical method

Intervention groups

1

Description
Intervention group: Patients in the main group recived Remdesivir consisting of two 100 mg vials, ie 200 mg intravenously, which is infused over a period of 30 minutes to two hours, on the first day of treatment with followed by 100 mg daily on the second, third, fourth and fifth day. Each vial is prepared with 19 cc of distilled water and diluted with 0.9% saline. Patients will be monitored daily and at the end of the 5-day treatment period
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr Fatemeh Ahmadi
Street address
Razi hospital, Felestin Ave, Amanieh Ave
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Postal code
6196514941
Phone
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Email
ahmadi-f@ajums.ac.ir

2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mehran Varnasseri
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mehdi Ahmadi Moghadam

Street address
Main building, Ahvaz University of Medical Science, Golestan

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6135539345

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ahmadi-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Roohangiz Nashibi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mehran Varnasseri

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

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Position
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Latest degree
Specialist

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