

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparison of Effectiveness of Remdesivir with Remdesivir and Interferon Beta-1 a Treatment Regime on Clinical Outcome of Covid 19 Patients

Protocol summary

Study aim

Comparison of the therapeutic effect of Remdesivir with a combination of interferon-beta 1A + Remdesivir on the clinical outcomes of patients with Covid-19

Design

A clinical trial with parallel, randomized, phase 3 groups per 100 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients over 40 years of age with moderate to severe severity of covid19 patients admitted to Shafa Hospital in Khorramabad in the year 1400 eligible for inclusion in the study are randomly divided into two groups of intervention and control and their clinical consequences will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients suspected of Covid19 infection who tested positive for PCR or despite the negative PCR test who have strong clinical evidence plus typical radiographic sign of Covid19 that is difficult to justify their symptoms based on other diseases.

Exclusion criteria: Dissatisfaction with participating in the study, History of severe renal failure, History of allergies to interferon or remdesivir, History of severe liver failure, Pregnancy, Lactation

Intervention groups

First intervention group: Receiving Remdesivir (with a loading dose of 200 mg on the first day and then a daily dose of 100 mg. Second Intervention group: Receiving Interferon-beta 1A with a dose of 12 million units + Remdesivir with a loading dose of 200 mg on the first day and then a dose of 100 mg daily

Main outcome variables

Duration of hospitalization, the Survival rate of 28 days from the time of hospitalization, The duration of recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048159N4**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Forouzan Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0239

Email address

ahmadpour.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Remdesivir with Remdesivir and Interferon Beta-1 a Treatment Regime on Clinical Outcome of Covid 19 Patients

Public title

Efficacy of Remdesivir in Comparison with Interferon Beta-1 a and Remdesivir in the Treatment of Covid 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized patients suspected to Covid19 infection SpO2 less than 93% The presence of respiratory symptoms (including shortness of breath, pain and pressure in the chest) older than 40 years

Exclusion criteria:

Dissatisfaction with participating in the study History of severe renal failure History of allergies to interferon or remdesivir History of severe liver failure Pregnancy Lactation

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients were randomly divided into two groups (Group A, receiving remdesivir alone and B, receiving remdesivir plus interferon beta 1-a) using a simple random method (using a random number table of the Excel function rand software). In Excel software, patients' names are entered in a column and then the RAND function is used to assign a random number to each cell. Then several cells are selected using the Index Rank formula.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan, Khorramabad, 3 km of Khorramabad Road, Tehran, Pardis University Complex, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Office of Research Ethics Committee

City

Khorramabad

Province

Lorestan

Postal code

381351698

Approval date

2021-07-10, 1400/04/19

Ethics committee reference number

IR.LUMS.REC.1400.090

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

Duration of hospitalization

Timepoint

7 -14 days

Method of measurement

Based on patient file information

Secondary outcomes

1

Description

The duration of recovery or the duration of entry into the disease stage

Timepoint

7-14 days

Method of measurement

Based on patient file information

2

Description

Survival rate of 28 days from the time of hospitalization

Timepoint

28 days after starting the study

Method of measurement

Interview with the patient or her family

3

Description

the amount of arterial oxygen saturation

Timepoint

Daily

Method of measurement

Using a device to measure the percentage of oxygen saturation

4

Description

Frequency of transfer to intensive care unit

Timepoint

Daily

Method of measurement

Under supervision

Intervention groups

1

Description

First intervention group: Receiving Remdesivir (Ronak Daru Pharmaceutical Company) with a loading dose of 200 mg on the first day and then a daily dose of 100 mg by intravenous injection for 7-14 days depending on the patient's clinical condition in addition to standard treatment according to national guidelines, (Which includes corticosteroids (dexamethasone or methylprednisolone) and anticoagulants (heparin or enoxaparin).)

Category

Treatment - Drugs

2

Description

Second Intervention group: Receiving Interferon-beta 1A (Sinagen Pharmaceutical Company) with a dose of 12 million units of subcutaneous injection every other day + Remdesivir (Ronak Pharmaceutical Company) with a loading dose of 200 mg on the first day and then a dose of 100 mg daily Intravenously for 7-14 days based on the patient's clinical condition in addition to standard treatment according to national guidelines, (Which includes corticosteroids (dexamethasone or methylprednisolone) and anticoagulants (heparin or enoxaparin).)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Forouzan Ahmadpour

Street address

Lorestan, Khorramabad, Piroozi St., Shafa Hospital

City

Khorramabd

Province

Lorestan

Postal code

133456789765432

Phone

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Email

info@shafahospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

Street address

Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road

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Khorramabad

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Email

falahi.e@lums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research and Technology of Lorestan 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor

Latest degree

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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

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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