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 Remedsivir with a combination of interferon-beta 1A + Remedsivir 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
ahmadpoor.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 remedsivir alone and B, receiving remedsivir 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
+98 66 3326 5020
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
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0239
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
Street address
Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0239
Email
ahmadpourforoz@yahoo.com

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
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0239
Email
ahmadpourforoz@yahoo.com

Person responsible for updating data

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
Street address
Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road
City
Khorramabad
Province
Lorestan
Postal code
381351698
Phone
+98 66 3312 0239
Email
ahmadpourforoz@yahoo.com

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