Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of interferon-beta 1a and Dexamethasone in hospitalized patients with Covid - 19.

Protocol summary

Study aim
Determination and comparison of the effect of beta interferon and dexamethasone in the treatment of patients with Covid-19

Design
A single-blind randomized clinical trial with a control group and parallel groups was performed on 160 patients. Block randomization method was used for randomization.

Settings and conduct
This study is being conducted at Shahid Jalil educational Hospital in Yasuj. Routine drugs with the possibility of affecting Covid 19 symptoms were used in both intervention 1 (Combination of Remedcivir, Interferon, and Dexamethasone) and intervention 2 or Control (Remedcivir and Dexamethasone) groups.

Participants/Inclusion and exclusion criteria
1. Definitive diagnosis of covid- 19 by infectious disease specialist and a positive PCR and spiral CT scan of the lung. 2. Inpatients who are at least 18 years old. 3. Hospitalized patients with pulmonary involvement in CT Scan if not intubated and not ventilated with NIV mask. 4. No history of pancytopenia. 5. Patients with a GFR of more than 30%. 6. Patients who are not pregnant. 8. Absence of liver inflammation.

Intervention groups
The intervention group1 includes patients who will receive a combination of Remedsivir, Interferon, and Dexamethasone, and the intervention group2 (Control) includes patients who will receive a combination of Remedsivir, and Dexamethasone.

Main outcome variables
The length of hospital stay Patient mortality. O2 saturation

General information

Reason for update

Acronym
مقایسه داروی بتا اینترفرون و دگزامتازون

IRCT registration information
IRCT registration number: **IRCT20150622022869N9**
Registration date: **2022-07-02, 1401/04/11**
Registration timing: **retrospective**

Last update: **2022-07-02, 1401/04/11**
Update count: **0**

Registration date
2022-07-02, 1401/04/11

Registrant information

Name
Moslem Sedaghattalab

Name of organization / entity
Yasuj University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of interferon-beta 1a and Dexamethasone in hospitalized patients with Covid - 19.

Public title
Comparison of Interferon-beta-1a and Dexamethasone on hospitalized patients with Covid-19.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of covid-19 by infectious disease specialist with a positive PCR and spiral ct scan of the lung. Hospitalized patients who are at least 18 years old.
Exclusion criteria:
Pregnant women Patients with GFR less than 30%. Patient with a history of Pancytopenia. Increased ALT more than 10 times.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **176**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method will be used. A total of 176 patients with Covid-19 who meet the inclusion criteria will be selected and randomly assigned to the two groups of intervention 1 and intervention 2. In block randomization, according to the total number of 176 patients and the existence of two groups, blocks with sizes of 2, 4, and 6 will be used. For example, if the size of block is 2, we will have two modes AB and BA (A and B are intervention groups 1 and intervention 2). In order to create sequences and concealment, online software with the following address will be used, and a special randomization code will be generated. Sealed Envelope Ltd. 2021. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 5 Jun 2022
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the person evaluating the outcome variables is unaware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی یاسوج
Street address
Shahid Motahari Boulevard
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591874934
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.YUMS.REC.1400.119

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
Arterial oxygen saturation
Timepoint
At the time of admission and discharge of the patient
Method of measurement
pulse oximeter device

Secondary outcomes

1

Description
Mortality rate
Timepoint
At the end of the intervention and completion of sampling
Method of measurement
By comparing the number of deaths in each group

2

Description
Duration of hospitalization
Timepoint
On the day of discharge from the hospital
Method of measurement
Number of hospitalization days

Intervention groups

1

Description
Intervention group: (combination of three drugs Remedsivir, Interferon, and Dexamethasone) Remedsivir drugs with a dose of 200 mg in the initial dose and then 100 mg daily for 5 days, Interferon-beta 1 alpha is given as a subcutaneous injection every other day for 4 doses (each vial contains 30 micro-grams of interferon is equivalent to 6 million international units) and dexamethasone at a dose of 8 mg daily intravenously.
Category
Treatment - Drugs

2

Description
Intervention group 2: Combination of Remdesivir and Dexamethasone) Remdesivir with a dose of 200 mg in the initial dose and then 100 mg daily for 5 days, and Dexamethasone at a dose of 8 mg daily intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital in Yasuj
Full name of responsible person
Moslem Sedaghattalab
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Shahid Qharani Boulevard
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yasuj 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
Yasouj University of Medical Sciences
Full name of responsible person
Moslem Sedaghattalab
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available