Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The assessment of therapeutic effect of β-interferon and Methylprednisolone in patients with COVID- 19: A quasi-experimental, double-blind, placebo-controlled study

Protocol summary

Study aim

The aim of this study was to evaluate the effectiveness of combination therapy of beta interferon and methylprednisolone in comparison with beta interferon on the recovery of patients with Covid-19.

Design

The double-blind clinical trial, sham- controlled clinical trial with parallel groups

Settings and conduct

People with Covid-19 admitted to Shahid Sadoughi Hospital in Yazd were divided into two groups after classification and matching based on age and sex. Both groups received medication on the first day of hospitalization according to the national protocol. During the days of hospitalization, the intervention group received 500 mg of methylprednisolone weekly and 0.44 mg of β-interferon daily subcutaneously. The control group received 0.44 mg of beta interferon daily subcutaneously.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18- 80 years old, Covid-19 infection based on high-resolution computed tomography findings, progressive and severe hypoxia based on blood oxygen saturation level less than 88% with a reservoir bag mask and flow of 15 liters, exacerbation of lymphopenia during hospitalization. Exclusion criteria: cardiovascular patients, grade 3 and more liver cirrhosis, autoimmune diseases, severe depression and psychosis, organ transplantation, kidney failure, pregnancy.

Intervention groups

Both groups received medication on the first day of hospitalization according to the national treatment protocol. For the intervention group, 500 mg methylprednisolone was given weekly and 0.44 mg β-interferon was administered subcutaneously daily. The control group received 0.44 mg of β- interferon subcutaneously daily.

Main outcome variables

Body temperature, blood pressure, respiration rate, O2 saturation, white blood cell, neutrophil, lymphocyte, platelet, erythrocyte sedimentation rate, C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048514N1**
Registration date: **2020-10-10, 1399/07/19**
Registration timing: **retrospective**

Last update: **2020-10-10, 1399/07/19**
Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Fatemeh sadat Aghaei meybodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

dr.meybodi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of therapeutic effect of β-interferon and Methylprednisolone in patients with COVID- 19: A quasi-experimental, double-blind, placebo-controlled study

Public title

Effect of β-interferon and methylprednisolone in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18- 80 years Covid-19 infection based on high-resolution computed tomography findings Progressive and severe hypoxia based on blood oxygen saturation level less than 88% with a reservoir bag mask and flow of 15 liters Exacerbation of lymphopenia during hospitalization

Exclusion criteria:

Cardiovascular patients Grade 3 and more liver cirrhosis Autoimmune diseases Severe depression and psychosis Organ transplantation Kidney failure Pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding was performed without informing the patients about the type of treatment and with the consent of each patient's family. The selected participant in an intervention group is informed about the implementation and duration of the intervention, but does not know the type of intervention and the main purpose of the study. An independent statistical researcher from the study team assigned eligible patients in a 1: 1 ratio to the interferon beta and methylprednisolone combination group or the interferon beta group. An independent pharmacist from the experimental team (from the pharmacy of Shahid Sadoughi Hospital) placed the labels with the study ID on separate numbered packages for the combined treatment of interferon beta and methylprednisolone and interferon beta based on a list (M & C codes). Not all clinical and laboratory staff, and participants were aware of the type of treatment assigned to each individual, and only the pulmonologist responsible for each patient was aware of the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of medical sciences

Street address

Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.SSU.REC.1399.040

Health conditions studied

1

Description of health condition studied

Covid- 19

ICD-10 code

U07.1

ICD-10 code description

Covid- 19

Primary outcomes

1

Description

Body temperature

Timepoint

At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis

Method of measurement

Vital Sign Monitoring Device

2

Description
Blood pressure
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Blood pressure cuff monitoring vital signs

3

Description
Respiration rate
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Vital Sign Monitoring Device

4

Description
O2 saturation
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Pulse oximeter

5

Description
White blood cells
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurements are performed using an automatic blood cell counting device.

6

Description
Neutrophil
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurements are performed using an automatic blood cell counting device.

7

Description
Lymphocytes
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurements are performed using an automatic blood cell counting device.

8

Description
Platelet
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurements are performed using an automatic blood cell counting device.

9

Description
Erythrocyte Sedimentation Rate
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurement is done by centrifugation.

10

Description
C-Reactive Protein
Timepoint
At the beginning of the study (before the intervention) and during the days of hospitalization on a daily basis
Method of measurement
Measurements are performed by ELISA method.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: On the first day of hospitalization according to the national treatment protocol, Keltra received 400 mg daily (morning and night), naproxen 250 mg (morning and night) and one dose of 400 mg hydroxychloroquine. In the intervention group, 500 mg of methylprednisolone was administered weekly and 0.44 mg of β-interferon daily subcutaneously.
Category
Treatment - Drugs

2

Description
Control group: On the first day of hospitalization according to the national treatment protocol, Keltra received 400 mg daily (morning and night), naproxen 250 mg (morning and night) and a dose of 400 mg hydroxychloroquine. In the control group, 0.44 mg of β-interferon was administered subcutaneously daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Shahid Sadoughi hospital
Full name of responsible person
Fatemeh sadat Aghaei meybodi
Street address
Shahid Sadoughi hospital, Ebne- Sina Ave., Yazd, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh sadat Aghaei meybodi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Others

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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