

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The assessment of therapeutic effect of $\beta$ -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  $\beta$ -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  $\beta$ -interferon was administered subcutaneously daily. The control group received 0.44 mg of  $\beta$ - 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  $\beta$ -interferon and Methylprednisolone in patients with COVID-19: A quasi-experimental, double-blind, placebo-controlled study

**Public title**  
Effect of  $\beta$ -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  $\beta$ -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  $\beta$ -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

**City**

Yazd

**Province**

Yazd

**Postal code**

8915887857

**Phone**

+98 35 3822 4000

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+98 35 3822 4100

**Email**

dr.meybodi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

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

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3146 2136

**Email**

mmirzaei@ssu.ac.ir

**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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Shahid Sadoughi hospital, Ebne- Sina Ave., Yazd, Iran

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## Person responsible for scientific 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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh sadat Aghaei meybodi

**Position**

Assistant Professor

**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