

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluating efficacy and safety of interferone $\beta$ -1a in the treatment COVID-19 infection

#### Protocol summary

##### Study aim

Evaluating efficacy and safety of interferone  $\beta$ -1a in the treatment COVID-19 infection

##### Design

This is a non-blinded randomized clinical trial.

##### Settings and conduct

This study will be done in Imam Khomeini Hospital of Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-75 years old persons Highly suspected of confirmed COVID-19 infection Exclusion criteria: History of drug allergy Uncontrolled baseline diseases including neuropsychiatric disorders, diabetes, thyroid disorders, heart disease Pregnancy and lactation Baseline liver failure

##### Intervention groups

Included patients will assign to intervention or control group according the permuted block randomization. Concomitant with the national proposed combination, the intervention group will receive interferon beta 1a, 44 mcg subcutaneously every other day for 14 days. Patents in the control group will receive only the national proposed combination. Patients will be followed every other day for response to the treatment and adverse reactions up to the end of treatment.

##### Main outcome variables

Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients' clinical outcomes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100228003449N28**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-26, 1399/01/07**

Update count: **1**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

###### Name

Hossein Khalili

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6695 4715

###### Email address

khalilih@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-15, 1398/12/25

##### Expected recruitment end date

2020-04-13, 1399/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating efficacy and safety of interferone  $\beta$ -1a in the treatment COVID-19 infection

##### Public title

Interferon in treatment of COVID-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with highly suspected or confirmed COVID-19 infection who are candid for hospitalized and starting triple-drug combination

**Exclusion criteria:**

History of drug allergy  
Uncontrolled baseline diseases including neuropsychiatric disorders, diabetes, thyroid disorders, heart disease  
Pregnancy and lactation  
Baseline liver failure

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done according to the blocks randomization method. Regarding to the sample size, 3 patients will be include in each block. Random sequences will be created by SAS software. This is a non-blinded randomized clinical trial.

**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 Tehran University Of Medical Sciences

**Street address**

Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614411

**Approval date**

2020-03-14, 1398/12/24

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.1052

**Health conditions studied**

**1**

**Description of health condition studied**

COVID-19 pneumonia

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Response to the treatment

**Timepoint**

Daily

**Method of measurement**

According the clinical, paraclinical and laboratory findings

**2**

**Description**

Complications of the treatment

**Timepoint**

Daily

**Method of measurement**

Interview and patient's record

**Secondary outcomes**

**1**

**Description**

Duration of hospitalization

**Timepoint**

End of the treatment

**Method of measurement**

Patient's record

**2**

**Description**

Clinical outcome

**Timepoint**

End of treatment

**Method of measurement**

Patient's record

**Intervention groups**

**1**

**Description**

Intervention group: Concomitant with the national corona treatment recommendation (hydroxychloroquine + lopinavir/ritonavir), patients will receive interferon beta, sub type 1a (CinnaGen Company) with dose of 44 mcg subcutaneously every other day for 14 days.

**Category**

Treatment - Drugs

## 2

### Description

Control group: Patients will receive the national corona treatment recommendation (hydroxychloroquine + lopinavir/ritonavir) for at least 5 days.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Complex

##### Full name of responsible person

Hossein Khalili

##### Street address

Keshavarz Boulevar

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۷۳۳۱۴۱

##### Phone

+98 21 6695 4715

##### Email

khalilih@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

02166706141

##### Phone

+98 21 8898 7381

##### Email

msahrai@sina.tums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Hossein Khalili

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417614411

#### Phone

0098216654715

#### Email

khalilih@tums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Hossein Khalili

#### Position

Professor

#### Latest degree

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

**When the data will become available and for how long**

One year after finishing the study, data will be published and will be available in databases

**To whom data/document is available**

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

**Under which criteria data/document could be used**

Other researchers are permitted to include the results in their systematic reviews and metaanalysis

**From where data/document is obtainable**

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

**What processes are involved for a request to access data/document**

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

**Comments**