

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Evaluating efficacy and safety of interferone β -1b (IFN β -1b) in the treatment of COVID-19

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluating efficacy and safety of interferone β -1b (IFN β -1b) in the treatment of COVID-19

Last update: **2020-03-25, 1399/01/06**

Update count: **2**

Design

This is a non-blinded randomized clinical trial. Included patients will be assigned to intervention or control group according the permuted block randomization.

Registration date

2020-03-16, 1398/12/26

Settings and conduct

This study will be done in Imam Khomeini Hospital.

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

Participants/Inclusion and exclusion criteria

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

Recruitment status

Recruitment complete

Funding source

Intervention groups

Concomitant with the national proposed combination, the intervention group will receive interferon β -1b (Zist Daru Daneh Company), 250 mcg subcutaneously every other day for 14 days. Patients 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.

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-05-14, 1399/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

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.

Scientific title

Evaluating efficacy and safety of interferone β -1b (IFN β -1b) in the treatment of COVID-19

General information

Reason for update

Edition of the interventions due to changes in the national protocol

Acronym

IRCT registration information

IRCT registration number: **IRCT20100228003449N27**

Registration date: **2020-03-16, 1398/12/26**

Public title

Interferon β in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with highly suspected or confirmed COVID-19 who are candid for hospitalization and starting triple-drug combination.

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

Age
From **18 years** old to **65 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
Patients with inclusion criteria of the study will be recruited in the intervention or the control group according the permuted block randomization (5 blocks and 3 patients in each block)

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.1398.1053

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 β , sub-type 1b (Zist Daru Daneh Company) with dose of 250 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 Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6695 4715

Email

khalil@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

+98 21 6695 4715

Email

khalil@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

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

+98 21 6695 4715

Email

khalilih@tums.ac.ir

Person responsible for updating data**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

+98 21 6695 4715

Email

khalilih@tums.ac.ir

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

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

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