Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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

Protocol summary

Study aim
Evaluating efficacy and safety of interferone β-1b (IFN β-1b) in the treatment of COVID-19
Design
This is a non-blinded randomized clinical trial.Included patients will be assigned to intervention or control group according the permuted block randomization.
Settings and conduct
This study will be done in Imam Khomeini Hospital.
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
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. 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
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**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-25, 1399/01/06**
Update count: **2**
Registration date
2020-03-16, 1398/12/26

Registrant information
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Hossein Khalili
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Recruitment status
Recruitment complete
Funding source

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

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

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
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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
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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
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Person responsible for updating data

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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
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 form 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 included 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