Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of interferon treatment in high-risk covid19 patients in Qom

Protocol summary

Study aim
Determination of interferon treatment in 19-year-old patients with high risk in Qom province.

Design
Clinical trial with control group, with parallel, non-blind, randomized group, phase 2 on 60 patients. Blockchain was used for randomization.

Settings and conduct
Patients admitted to Shahid Beheshti and Forghani Hospitals with COVID 19 By receiving oxygen by reserve bag, they have less than 94% oxygen saturation Provided you have an entry criterion, According to the pilot study, in two groups of 30 people, it was selected as control and intervention.And enter the study 24 hours after hospitalization And randomly enter the blockade allocation into one of two treatment groups; n addition to receiving treatment protocol from the Ministry of Health, the intervention group will be treated with interferon after obtaining informed consent, and the second group will be treated only with the protocol of the Ministry of Health.

Participants/Inclusion and exclusion criteria
Entry requirements: Adulthood, laboratory confirmation of Covid19 infection, dysfunction of the new organ related to Covid19 Conditions of non-entry: intent to commit suicide, sensitivity, or drug sensitivity reaction, ALT above 5 times normal. Use of drugs that are contraindicated with lopinavir / ritonavir, pregnancy, known HIV infection, all vulnerable groups.

Intervention groups
In addition to receiving treatment protocol from the Ministry of Health, the intervention group underwent interferon treatment after obtaining conscious consent. And the second group is only treated by the protocol of the Ministry of Health.

Main outcome variables
Primary consequences (death within 30 days of hospitalization) and secondary consequences, for example, Results of RT-PCR in lower respiratory samples

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20160118026097N3**
Registration date: **2020-05-31, 1399/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-31, 1399/03/11**
Update count: **0**

Registration date
2020-05-31, 1399/03/11

Registrant information

Name
Jamshid Vafaeemanesh

Name of organization / entity
Qom University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 252931933

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j.vafaeemanesh@muq.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of interferon treatment in high-risk covid19 patients in Qom

Public title
The effect of interferon on the treatment of covid19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Laboratory confirmation of Covid19 infection with reverse transcription polymerase chain reaction (RT-PCR) from any diagnostic sampling source A new organ dysfunction related to Covid19 Being an adult

Exclusion criteria:
Intention to commit suicide (interfering with interferon (IFN) -b1b). Sensitivity or sensitivity reaction to Lupinavir / Ritonavir or IFN-β1b recombinant, including toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema or angioedema syndrome. ALT above 5 times normal Use of drugs that are contraindicated with lopinavir / ritonavir and should not be substituted or discontinued during the study period, such as CYP3A inhibitors. pregnancy.Eligible female participants are tested at gestational age before enrolling in the study for pregnancy. HIV Vulnerable groups

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization through block allocation

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of qom University of Medical Sciences

Street address
qom

City
qom

Province
Ghoum

Postal code
3719964797

Approval date
2020-04-28, 1399/02/09

Ethics committee reference number
IR.MUQ.REC.1399.089

Health conditions studied

1

Description of health condition studied
COVID19

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
death within 30 days of hospitalization

Timepoint
every day

Method of measurement
View

Secondary outcomes

1

Description
Days without organ support (for example, supplemental O2, mechanical ventilation, dialysis and vasopressors)

Timepoint
Time interval: 28 days

Method of measurement
View

2

Description
Results of RT-PCR in lower respiratory samples

Timepoint
Time interval: At the time of entering the study and one week after treatment and repetition every week until the negative sample of the period

Method of measurement
test

3

Description
Body Failure Assessment Scores (SOFA)

Timepoint

Time frame: days 1, 3, 5, 7, 14 and 28)

Method of measurement

check list

Intervention groups

1

Description

Intervention group: In addition to receiving treatment protocol from the Ministry of Health, after obtaining informed consent, it will be treated with interferon.

Category

Treatment - Drugs

2

Description

Control group: They are treated only by the protocol of the Ministry of Health

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

beheshti & forghani hospital

Full name of responsible person

hasan adeli

Street address

beheshti blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

jamsheed vafaeemanesh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
jamshid vafaeemanesh

Position
Associate professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after people have not been identified

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used
According to the rules of the COPE

From where data/document is obtainable
jvafaeemanesh@yahoo.com

What processes are involved for a request to access data/document
Email the responsible author

Comments
no