

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; in 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 Vafaemanesh

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 252931933

Email address

j.vafaemanesh@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

Ghous

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

City

qom

Province

Ghous

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3719964797

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+98 25 3612 2526

Email

adeli@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

hasan adeli

Street address

beheshti blv

City

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Province

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Phone

+98 25 3612 2526

Email

adeli@muq.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

jamsheed vafaemanesh

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 vafaemanesh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Email

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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

jvafaemanesh@yahoo.com

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

Email the responsible author

Comments

no