Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

effect of Interfron-beta1(zifron) on clinical improvement and prognosis of COVID-19 in Tabriz Imam-Reza hospital

Protocol summary

Study aim

Evaluation of the effect of Betafron on reducing and preventing the progression of respiratory failure as well as organs failure and death of COVID-19 disease.

Design

Clinical trial with parallel control group , randomisation by balanced block method, phase 2 on 60 COVID-19 patients

Settings and conduct

60 COVID-19 patients admitted to Tabriz Imam Reza Hospital will be divided in 2 groups: treatment and control. In randomization by balanced block method, first,we will define quadruple blocks with group (A) and (B) arrangements, then we will select each of the blocks using the table of random numbers, and prepare 4 patients in the arrangement of (A) and (B) group in the selected block enrolled to the study. We will Continue this process to complete patients..Both groups will be treated by Hydroxychloroquine and Kaletra. In 30 intervention group patients , interferon beta 1 (zifron) 250 micrograms subcutaneously every other day for up to 5 doses will be added, but not in other 30 control group patients. Oxygenation, need for mechanical ventilation,and mortality will be monitored. Outcome, considering improvement in respiratory failure, need for mechanical ventilation, and in hospital mortality will be compared in 2 groups.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1. Respiratory rate more than 24 per minute 2. Pao2 / FIO2 less than 300 exclusion criteria: 1. Pregnancy 2. History of allergy to interferon-beta 1 compounds (zifron) 3. History of advanced liver disease and liver enzymes three times normal 4. History of severe depression with suicidal thoughts

Intervention groups

30 patients in intervention group will be treated with antivirals and interferon beta1. And control group will be treated only with antivirals.

Main outcome variables

Arterial oxygen saturation P / F ratio mechanical ventilation mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200406046968N3**
Registration date: **2020-05-08, 1399/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**
Update count: **0**

Registration date

2020-05-08, 1399/02/19

Registrant information

Name

Haleh Mikaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3329 6024

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halehmikaeili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
effect of Interfron-beta1(zifron) on clinical improvement and prognosis of COVID-19 in Tabriz Imam-Reza hospital

Public title
effect of Interfron-beta1(zifron) on clinical improvement and prognosis of COVID-19 in Tabriz Imam-Reza hospital

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
respiratory rate> 24 / min pao2 / Fio2< 300
Exclusion criteria:
Pregnancy history of Sensitivity to interferon-beta 1 compounds (zifron) History of advanced liver disease and liver enzymes three times normal history of severe depression or suicidal thought

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by permuted (balanced) block randomization method. At the beginning, we will define quadruple blocks with group (a) and group (b) arrangements, and then we will select each of the blocks using the table of random numbers, and after each black determination, prepare 4 patients in the arrangement of(A) and (B) group in the selected block enrolled to the study. Then 4 other patients will be selected through the other block. We will Continue this process to complete patients.

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
Regional Research Ethics Committee (Humanities Studies)
Street address
Tabriz / Golgasht St. / Tabriz University of Medical Sciences Central Building No. 2 / Third Floor Deputy of Research and Technology
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766

Approval date
2020-04-13, 1399/01/25

Ethics committee reference number
IR.TBZMED.REC.1399.019

Health conditions studied

1

Description of health condition studied
COVID-19 diseaese

ICD-10 code
U07.2

ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
oxygenation

Timepoint
daily

Method of measurement
pulse oximetery

Secondary outcomes

1

Description
P/F ratio

Timepoint
daily

Method of measurement
ABG

2

Description
need for mechanical ventilation

Timepoint
daily

Method of measurement
file

3

Description

in hospital mortality

Timepoint

daily

Method of measurement

file

Intervention groups

1

Description

Intervention group: 30 COVID-19 patients with inclusion criteria will be treated with 250 micro grams of betafron (Zifron Zist Darou Danesh) Subcutaneously every other day up to 10 days or 5 dosages in addition to antivirals including hydroxychloroquine 400 mg,bid stat. and Kaletra 2 tablet bid for 10 days.

Category

Treatment - Drugs

2

Description

Control group: 30 COVID-19 patients will be treated only with antivirals including hydroxychloroquine 400 mg,bid stat and Kaletra 2 tablet bid for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mikaeili Haleh

Street address

University Street in front of the Central Organization of Tabriz University of Medical Sciences

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info@imamreza.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zist Daru Danesh Company

Full name of responsible person

Hooshmand Ilka

Street address

No. 33, First Floor, Corner of Siboyeh St., Ibn Yamin St., North Sohrevardi St.

City

Tehran

Province

Tehran

Postal code

1555633114

Phone

+98 21 4231 8100

Email

info@zistdaru.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Daru Danesh Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mikaeili Haleh

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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Tabriz University of Medical Sciences
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Position
Associate professor
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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
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 data related to the study of the effect of interferon-beta 1 (zifron) on clinical improvement and prognosis of patients with COVID-19 will be shared in Imam Reza (AS) Hospital in Tabriz.
When the data will become available and for how long
Since the summer of 1399
To whom data/document is available
Researchers and all treatment staff
Under which criteria data/document could be used
For treatment
From where data/document is obtainable
Dr. Mikaeili haleh
What processes are involved for a request to access data/document
After finishing the work and getting the result
Comments