Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of treatment regimen containing beta-1-b interferon on the COVID-19 patients with mild and severe symptoms and comparing it with interferon-free treatment regimen

Protocol summary

Study aim

evaluation of the effect of treatment regimen contains Intrefron beta-1-b on the Covid 19 patients compared with those patients who received treatment regimen without interfron.

Design

Open label, controlled and paralleled non-randomized clinical trial with control group phase 2-3 on 150 patients as two intervention and control groups.

Settings and conduct

Sampling for arterial oxygen pressure and other blood sample parameters (LDH, ESR,, CBC, D-dimer, Lymphocyte and neutrophil absolute count) will be measured at the beginning of hospitalization and the end of treatment course. Severity of lung involvement assessed by CT scan of chest. This study will be held on the patient hospitalized in Shahid Mohammadi hospital, Bandar Abbas, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive real time PCR test from nasopharyngeal and oropharyngeal swabs, Degree of lung involvement by CT-severity scoring, Arterial Po2 pressure less than 93 mmHg, and respiratory rate more than 30 times/min. Exclusion criteria: Chronic diseases like diabetes, asthma, cardiovascular disorder, Malignancy and other condition like pregnancy, breastfeeding and corticosteroid therapy.

Intervention groups

90 patients will be selected as an intervention group and 50 patients as a control group. The intervention group will be received routine treatment regimen plus Interferon beta-1-b and control group will be received routine regimen only.

Main outcome variables

CRP - LDH - ESR - WBC - Neutrophil count-Lymphocyte count- D-dimer - CT severity score- Po2 -

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048894N1**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-15, 1399/09/25**
Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name
Afshin Samiei
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 76 3371 0373
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afshin.samiei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of treatment regimen containing beta-1-b interferon on the COVID-19 patients with mild and severe symptoms and comparing it with interferon-free treatment regimen

Public title
Effect of Interferon beta-1-b on COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive result of Real time PCR CT severity scoring P o2 < 93mmHg Respiratory rate more than 30 time per minute.

Exclusion criteria:
Diabetes Cardiac diseases pregnancy Malignancy Consumption of corticosteroids

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Hormozgan University of Medical Sciences

Street address
Emam Hossein Blvd.

City
Bandar Abbas

Province
Hormozgan

Postal code
7919693116

Approval date
2020-08-15, 1399/05/25

Ethics committee reference number
IR.HUMS.REC.1399.259

Health conditions studied

1

Description of health condition studied
Covid 19

ICD-10 code
U07.1

ICD-10 code description
Covid 19 , Virus Identified

Primary outcomes

1

Description
CT severiity score

Timepoint
At the beginning and the end of study

Method of measurement
By CT scan

2

Description
ABG - Pao2

Timepoint
At the beginning and at the end of study

Method of measurement
ABG assay system

3

Description
D-dimer that is fibrin degradation product (FDP)

Timepoint
At the beginning and at the end of study

Method of measurement
By ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Subcutaneous administration of 250 microgram IFN beta-1-b every other day

Category
Treatment - Drugs

2

Description
Control group: Control group will receive Covid-19 routine prescription.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Dr.Negahi
Street address
بلوار جمهوری اسلامی
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
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Email
research@hums.ac.ir
Web page address
https://resv.hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Afshin Samiei
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
only outcome information will be presented

When the data will become available and for how long
3 month after publishing the results

To whom data/document is available
everyone

Under which criteria data/document could be used
not restricted

From where data/document is obtainable
afshin.samiei@gmail.com

What processes are involved for a request to access data/document
sending an E-mail

Comments