

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 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)

Phone

+98 76 3371 0373

Email address

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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Web page address<https://shmh.hums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymour Aghamolaei

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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

Ph.D.

Other areas of specialty/work

Immunology

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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