

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A Single-blind, randomized controlled trial

Protocol summary

Study aim

Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A randomized and Single-blind clinical trial

Design

a single-blind randomized controlled study with two parallel arms with 50 patients in each.

Settings and conduct

The study will be conducted at Shohada Hospital. Patients will be randomly assigned to the national protocol with or without sofosbuvir in two parallel groups. Study outcomes will be evaluated over a one-month period. Patients and outcome assessors will be blind using the random codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both genders, aging from 18 to 80 Y.O. who are admitted in hospital, showing at least one of these criteria: Fever (Oral temperature $\geq 38^{\circ}\text{C}$), Respiratory rate $>24/\text{min}$, $\text{O}_2\text{Sat} < 93\%$ in room air or the $\text{PaO}_2/\text{FiO}_2$ ratio $\leq 300\text{mgHg}$, Laboratory (RT-PCR) confirming the infection with 2019-Covid Virus, Lung involvement in CT-Scan less than 50% (in compliance with the involvement of moderate COVID19), $5 \leq \text{days}$ since onset of the COVID19 symptoms ≤ 10 Exclusion criteria: History of allergic reaction to the drugs used in this clinical trial in a pregnancy or breast feeding status, test Receipt of any experimental treatment for COVID-19 before hand, Heart rate $< 60/\text{min}$, currently on amiodarone prescription, presence of multi organ failure evidence, in need of mechanical ventilation, estimated glomerular filtration rate $< 50 \text{ mL}/1.73 \text{ m}^2/\text{min}$, admitted in ICU ward, who are in shock

Intervention groups

50 patients admitted in COVID ward from 3/4/2021 with definitive diagnosis of moderate COVID19. For one arm (50 patients) the treatment regimen will consist of interferon+sofosbuvir+national protocol for COVID19 and for the other arm (50 patients) it will be interferion+national protocol for COVID19

Main outcome variables

Duration of remission, by length of stay and discharge (if recovery happens)/death

General information

Reason for update

اصلاح نحوه کورسازی در مطالعه از دوسر کور به یک سر کور

Acronym

IRCT registration information

IRCT registration number: **IRCT20180302038915N1**

Registration date: **2021-04-05, 1400/01/16**

Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **1**

Registration date

2021-04-05, 1400/01/16

Registrant information

Name

Rama Bozorgmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

r.bozorgmehr@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-14, 1400/01/25

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A Single-blind, randomized controlled trial

Public title

Safety and efficacy of sofosbuvir in the moderate COVID19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both genders Age ranging from 18 to 80 Y.O. who are admitted in hospital showing at least one of these criteria: Fever (Oral temperature ≥ 38 °C) , Respiratory rate >24 /min , O₂Sat $<93\%$ in room air or the PaO₂/FiO₂ ratio ≤ 300 mgHg Laboratory (RT-PCR) confirming the infection with 2019-Covid Virus Lung involvement in CT-Scan less than 50 % (in compliance with the involvement of moderate COVID19) 5 \leq days since onset of the COVID19 symptoms ≤ 10

Exclusion criteria:

History of allergic reaction to the drugs used in this clinical trial in a pregnancy or breast feeding status test Receipt of any experimental treatment for COVID-19 before hand Heart rate < 60 /min currently on amiodarone prescription presence of multi organ failure evidence in need of mechanical ventilation estimated glomerular filtration rate < 50 mL/1.73 m²/min admitted in ICU ward who are in shock

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

by block randomization technique , allocation of the patients will be completely randomized via using a software. there will be 2 arms

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be Single- blinded. Care providers and data analyzers will be blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-Chancellor in Research Affairs- Shahid Beheshti University of Medical sciences

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Aarabi st , Evin

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1985717434

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.SBMU.RETECH.REC1399.1322

Health conditions studied**1****Description of health condition studied**

COVID19

ICD-10 code

U07.1

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Time to reach clinical recovery

Timepoint

after 10 days on treatment initiation

Method of measurement

daily physical exam, assessing vanishing of tachypnea ,blood saturation of O₂(using pulse-oximeter) , fever(using thermometer)

Secondary outcomes**1****Description**

The rate of patients who need to admit in ICU ward

Timepoint

14 days after Treatment initiation

Method of measurement

physical exam and paraclinical evaluation

2

Description

The rate of patient expiry in each arm

Timepoint

14 days after treatment initiation

Method of measurement

questionnaire

3

Description

remission of clinical symptoms in each arm

Timepoint

14 days after treatment initiation

Method of measurement

physical exam (thermometer and pulse-oximeter)

Intervention groups

1

Description

Intervention group: all the patients are required to fill the consent form to be able to enter the trial. 50 patients admitted in the COVID ward with definitive moderate COVID19 diagnosis and randomly divided into two arms(each with 50 patients). in the intervention arm, the treatment regimen will consist of sofosbuvir, interferon beta 1a, and national protocol for COVID treatment. interferon beta 1a 44 micrograms will be administered subcutaneously 3-5 doses a day and sofosbuvir 400 mg orally and daily for 10 days and paraclinical tests and vital signs and blood O2 saturation will be assessed according to the plan by experienced health providers

Category

Treatment - Drugs

2

Description

Control group: All the patients are required to fill the consent form to be able to enter the trial. 50 patients admitted to the COVID ward with definitive moderate COVID19 diagnosis and randomly divided into two arms(each with 50 patients). in the intervention arm, the treatment regimen will consist of interferon beta 1a and national protocol for COVID treatment. interferon beta 1a 44 micrograms will be administered subcutaneously 3-5 doses a day for 10 days and paraclinical tests and vital signs and blood O2 saturation will be assessed according to the plan by experienced health providers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Tajrish hospital

Full name of responsible person

Rama Bozorgmehr

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Shahrdari Aven. , Tajrish Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Headquarters Building 2, Floor 5, Research and Technology Department

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fariba Ghorbani

Position

Researcher, MD, PhD

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Dr, Masih Daneshvary Hospital, Niavaraan,
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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farbod Amiri

Position

Medical Intern

Latest degree

Medical doctor

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Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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medicine

Latest degree

Subspecialist

Other areas of specialty/work

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Fax**Email****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available