Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 from18 to 80 Y.O. who are admitted in hospital , showing at least one of these criteria: Fever (Oral temperature ≥ 38 ℃) , Respiratory rate >24/min , O2Sat<93% in room air or the Pa02/Fi02 ratio ≤300mgHg , 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 ≤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 0mL/1.73 m2/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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+98 21 2271 8001

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r.bozorgmehr@sbmu.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 from18 to 80 Y.O. who are admitted in hospital showing at least one of these criteria: Fever (Oral temperature ≥ 38 ℃) , Respiratory rate >24/min , O2Sat<93% in room air or the Pa02/Fi02 ratio ≤300mgHg 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 ≤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 0mL/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
Street address
Aarabi st , Evin
City
Tehran
Province
Tehran
Postal code
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
Street address
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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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Mpajouhesh@sbmu.ac.ir
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
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Other areas of specialty/work
Medical Biotechnology
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Latest degree
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Person responsible for updating data

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farbod_am@sbmu.ac.ir

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