Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of clinical course of the disease in patients with Covid-19 infection with or without antibiotics

Protocol summary

Study aim

Determining the clinical course of the disease in patients with Covid-19 infection with or without antibiotics

Design

A clinical trial with a control group, with parallel groups, three-way blind, randomized with random allocation software, was performed on 90 patients.

Settings and conduct

The study is performed on patients admitted to Hajar Hospital in Shahrekord with Covid disease and patients are divided into control and intervention groups. First, the clinical signs of Arterial oxygen level (O2Sat), temperature, respiratory rate and ESR, CRP, Ferritin and procalcitonin (PCT) tests are recorded from both groups of patients. Patients with a positive PCT test need to start antibiotics and do not enter the study. Patients in the control group receive the Remdesivir drug regimen and in the intervention group receive the Remdesivir and antibiotics. Antibiotics are cephalosporins and fluoroquinolones. ESR, CRP, Ferritin tests, fever, respiration rate, and oxygen saturation are checked one week later, and clinical signs, including fever, respiration rate, and oxygen saturation, are checked two weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with confirmed molecular test (PCR positive); Blood oxygen saturation level SpO2 <93% in room air; Patients with moderate pulmonary involvement in radiological studies; No need for antibiotics in terms of indicator bacterial infection (PCT negative) Criteria for not entering: Patient dissatisfaction with participation in the study; Need for antibiotics in terms of bacterial infection index (PCT positive)

Intervention groups

In the control group, Remdesivir and in the intervention group, in addition to Remdesivir, antibiotics are used.

Main outcome variables

main outcome variables include: ESR; CRP; Ferritin; PCT (procalcitonin test); Arterial oxygen saturation (O2Sat); Temperature (T); Respiratory rate (RR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210510051248N1**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

Hamid Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of clinical course of the disease in patients with Covid-19 infection with or without antibiotics

Public title
Comparison of clinical course of the disease in patients with Covid-19 infection with or without antibiotics
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with confirmed molecular test (PCR positive) Blood oxygen saturation level SpO2 <93% in room air Patients with moderate pulmonary involvement in radiological studies No need for antibiotics in terms of indicator bacterial infection (PCT negative)
Exclusion criteria:
Patient dissatisfaction with participation in the study Need for antibiotics according to the indication of bacterial infection (PCT positive)
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomized using random allocation software. In the software, the number of groups and the number of samples and groups are determined. Numbers 1 to 90 are then randomly assigned to the control group and the intervention group. Control group : A Intervention group : B
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants will be divided into control groups (A) and intervention (B) using random allocation software. Envelopes are then prepared according to the number of people participating in the study, and numbers 1 to 90 are written on the envelopes and placed in each envelope using software A and B. In this way, with the arrival of each person, an envelope dedicated to that person is opened and according to the option inside the envelope, the person is assigned to one of the intervention or control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی شهرکرد
Street address
خیابان کاشانی دانشگاه علوم پزشکی شهرکرد
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2021-11-16, 1400/08/25
Ethics committee reference number
IR.SKUMS.REC.1400.181

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
Erythrocyte Sedimentation rate
Timepoint
Measurement of erythrocyte sedimentation rate on the first and seventh days
Method of measurement
Measurement of erythrocyte sedimentation rate by the device ESR analyzer semimex

2

Description
C-reactive protein
Timepoint
Measurement of C-reactive protein on the first and seventh days
Method of measurement
Measurement of C-reactive protein with the device BT-3500 And BT-3000

3

Description

ferritin

Timepoint

Measurement of ferritin on the first and seventh day

Method of measurement

Measurement of ferritin with the device Cobas

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vial Remdesivir 100 mg Ronak Pharmaceutical Company for 5 days, 200 mg on the first day and 100 mg on the second to fifth days; Levofloxacin 750 mg tablets Abidi Pharmaceutical Company for 5 days, 750 mg daily; Vial Ceftriaxone 1 gr Exir Pharmaceutical for 5 days, 1 gr every 12 hours;

Category

Treatment - Drugs

2

Description

Control group: Vial Remdesivir 100 mg Ronak Pharmaceutical Company for 5 days, the first day 200 mg and the second to fifth days 100 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital in Shahrekord

Full name of responsible person

Ahmad Raesi

Street address

Hajar Hospital, Parastar Street

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Hajar-Hospital@skums.ac.ir

Web page address

https://hajarhp.skums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Kashani St. Headquarters of Shahrekord University of Medical Sciences

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Web page address

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Ahmad Raesi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Hamid Mohammadi

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Resident of Internal Medicine

Latest degree

Medical doctor

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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

Information about the main outcome can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Dr. ahmad raisi

Under which criteria data/document could be used

The documents can be used after printing the results

From where data/document is obtainable

The data can be used by referring to the e-mail address

What processes are involved for a request to access data/document

Access period starts 6 months after the trsults are published

Comments