

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 38 3338 3121

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st-mohammadi.h@skums.ac.ir

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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Email

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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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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Name of organization / entity

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Full name of responsible person

Ahmad Raesi

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

Other areas of specialty/work

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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 results are published

Comments