

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Evaluation the effect of raltegravir, and raltegravir/interferon beta combination on covid 19 patients admitted in Peymanieh hospital of Jahrom in 2020

Protocol summary

Study aim

The effect of the Raltegravir and Raltegravir/interferon beta in patients with COVID-19

Design

This study is one blinded clinical trial. The study population will be all patients infected with COVID-19 admitted to Peymanieh hospital of Jahrom. 60 eligible patients will be selected conveniently and randomly assigned to three intervention groups.

Settings and conduct

The study, which will be conducted at Paymaneh Hospital of Jahrom, is one-blinded one that participants are unaware of the type of treatment they receive. At the beginning of the study, the patient's clinical status is recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Absolute lymphocyte count <1100 / ML or SaO₂ <93 Exclusion criteria: Pregnancy or breast-feeding The physician's decision that the trial is not in the patient's interest Any circumstances that do not allow the treatment protocol to be followed easily A history of severe liver disease including cirrhosis or ALT or AST levels more than five times normal Drugs that are contraindicated with standard treatment or raltegravir interferon beta and cannot be discontinued

Intervention groups

1- The control group will receive 400 mg of hydroxychloroquine. 2- in addition to 400 mg of hydroxychloroquine will receive 400 mg of Raltegravir (twice in a day) for 10 days. 3-in addition to 400 mg of hydroxychloroquine and 400 mg of Raltegravir (twice in a day) for 10 days, will receive 44 micro-gram interferon beta every other day

Main outcome variables

Clinical status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200412047042N1**

Registration date: **2020-06-11, 1399/03/22**

Registration timing: **prospective**

Last update: **2020-06-11, 1399/03/22**

Update count: **0**

Registration date

2020-06-11, 1399/03/22

Registrant information

Name

Samaneh Zolghadri Jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5437 2000

Email address

z.jahromi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-19, 1399/03/30

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of raltegravir, and raltegravir/interferon beta combination on covid 19 patients admitted in Peymanieh hospital of Jahrom in 2020

Public title

Evaluation the effect of raltegravir, and raltegravir/interferon beta combination on covid 19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

confirmed diagnosis of COVID19 with RT-PCR hospitalized patients

Exclusion criteria:

Patients with severe dyspnea require mechanical ventilation or hospitalization in intensive care units and patients with treatment-resistant hypoxemia or those with severe underlying disease Pregnancy or breastfeeding Drug allergy Patient dissatisfaction

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A random number table and block randomization method is used. In this method 60 eligible patients are assigned into 20 blocks of 3 patients. Then, each of the 3 patients in the block is randomly assigned to take Raltegravir, Raltegravir/interferon beta or chloroquine, so that 20 patients assigned to each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients will be kept blind to the type of treatment. Package for drugs is labeled with code A, B or C. Other specifications on the labels are identical. Patients are aware that they are the interventional groups but they are not aware of the type of group they are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical Sciences

Street address

Motahari

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

IR.JUMS.REC.1399.028

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 disease

Primary outcomes

1

Description

In this study, Sequential Organ Failure Assessment (SOFA) will be used to assess the severity of the disease. In this criterion, respiratory systems (PaO₂ / Fio₂ measurement), coagulation (platelet count), liver (bilirubin level), cardiovascular (hypotension), central nervous system (CNS) and kidney (creatinine level or urinary tract) Will be reviewed. Each parameter is graded on a 5-point Likert scale (score between zero and 4). The total score is between zero and 28. Higher scores indicate a worse patient condition.

Timepoint

Before and after the intervention

Method of measurement

The data will be collected using the information in the patient's file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In addition to standard treatment (400 mg of hydroxychloroquine) in the amount of 400 mg of raltgravir twice a day for 10 days and will receive tablets.

Category

Treatment - Drugs

2

Description

Intervention group 2: In addition to standard treatment (400 mg of hydroxychloroquine) and 400 mg of raltgravir for 10 days, 44 micrograms interferon beta at a dose of 44 micrograms as a subcutaneous injection every other day.

Category

Treatment - Drugs

3

Description

Control group: Receive the usual treatment according to the recommendation of the National Committee (400 mg of hydroxychloroquine)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Paymanieh Hospital

Full name of responsible person

Dr Rahim Raoufi

Street address

motahari

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7414846199

Phone

+98 71 5434 0409

Email

sarahim1513@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Dr Kavous Solhjo

Street address

Motahari

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Jahrom

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Postal code

74148461999

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+98 71 5444 7760

Email

Pazhuheshi@jums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Dr Rahim Raoufi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Shahid Motahari Boulevard

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sarahim1513@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Samaneh Zolghadri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

One month after publishing

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

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

Documentation will be emailed within a 30-day timeframe

Comments

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Samaneh Zolghadri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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