Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

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 tin 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 Pymanieh 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 fives 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)

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+98 71 5437 2000

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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 chloroqine, 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 raltagravir 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 raltagravir 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Dr Kavous Solhjoo
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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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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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Person responsible for updating data

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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