Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy and safety of recombinant erythropoietin on the improvement of hospitalised COVID-19 patients

Protocol summary

Study aim
This study aims to investigate the effect of recombinant erythropoietin on the recovery process of COVID-19 patients.

Design
concealed, randomized, single blinded, phase 2 controlled clinical trial with two arm parallel group design of 20 patients, using the placebo in the control group.

Settings and conduct
This study will be performed at Shahid Mohammadi Hospital in Bandar Abbas. Patients enter the study after obtaining written consent, but will not know which group they belong to.

Participants/Inclusion and exclusion criteria
All positive COVID-19 patients who have Hb≤9 and at least one of the severe COVID-19 symptoms and are willing to cooperate in this project will be included in the study. Patients with a history of coronary heart disease, thrombosis, deep vein thrombosis, chronic lung disease, diabetes mellitus, weakened immune system, end stage renal disease, liver disease, and patients with a history of taking oral contraceptive pills, systolic blood pressure more than 160 mm Hg, diastolic blood pressure more than 90 mm Hg and age over 65 and erythropoietin above 500 are excluded.

Intervention groups
Patients are divided into two groups. In group A, the standard treatment for COVID-19 patients with recombinant erythropoietin is prescribed. In group B, patients receive standard COVID-19 treatment with the placebo.

Main outcome variables
Patient clinical symptoms, Laboratory examinations of patients and Hemoglobin

General information

Reason for update
The expected recruitment end date was on 2020/12/21 but since we had a wide and careful exclusion criteria because of the adverse reactions of the medication, the recruitment (for both cases and controls) was not so easy and did not finish on the expected date and we are still recruiting now. Recruitment began on 2020/8/17 and the updated expected recruitment end date is 2021/8/1.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200509047364N1**
Registration date: **2020-08-09, 1399/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-26, 1400/03/05**
Update count: **2**

Registration date
2020-08-09, 1399/05/19

Registrant information

Name
Dariush Hooshyar

Name of organization / entity

Country
Iran (Islamic Republic of)

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dariush.hooshyar@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2021-08-01, 1400/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy and safety of recombinant erythropoietin on the improvement of hospitalised COVID-19 patients

Public title
Effect of erythropoietin on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All definitively positive COVID-19 patients with Hb≤9. Having at least one of the severe symptoms of COVID-19, including tachypnea (breathing rate> 30 beats per minute), hypoxemia (O2 ≤93 saturation, the partial pressure ratio of arterial oxygen <300), Lung infiltration (> 50% of lung field within 24 to 48 hours), progressive lymphopenia, LDH>245 U/I, CRP>100

Exclusion criteria:
Patients with a history of coagulopathy Patients with a history of thrombosis Patients with a history of deep vein thrombosis Patients with a history of chronic lung disease Patients with a history of diabetes mellitus Patients with weakened immune systems Patients with a history of end stage renal disease Patients with liver disease Patients with a history of taking oral contraceptive pills (OCPs) Patients with systolic blood pressure greater than 160 mmHg Patients with diastolic blood pressure greater than 90 mmHg Patients over 65 years of age Patients with erythropoietin above 500 Patients with a history of myocardial infarction or unstable angina Patients with a history of malignancy

Age
To **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Before assigning groups to individuals eligible to participate in the study, informed consent is completed for grouping individuals. the person who has no role in admitting patients and assigning patients to random codes preparing random sequences using online tools (https://www.sealedenvelope.com/) and by permuted block randomization method. Individualized random allocation is done in blocks with sizes 2 and 4, and with stratification based on gender. eligibility criteria are monitored by the person responsible for admitting patients. Codes in a random sequence are assigned to patients by the treatment team without knowing that each code is in the intervention or placebo group. Patient codes are then matched to randomly generated sequence information for interventions. (randomization concealment is done by the treatment team without informing the person responsible for admitting patients and the person who prepared the random sequence.)

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, all participants are aware of participating in this study and enter the study with their consent. All participants are unaware of which group of this study they are in and after grouping patients in the groups, Patients receive recombinant erythropoietin in the treatment group and receive a placebo in the control group. The lead researcher, health care personnel, data collection officials, and those who evaluate the outcome are aware of the grouping of patients. Those who prepare the draft of the article are unaware of the groupings if they do not cooperate in the above cases.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Deputy of Research and Technology, Hormozgan University of Medical Sciences, Shahid Chamran Boulevard, Bandar Abbas, Hormozgan, Iran

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Province
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Postal code
7916613885

Approval date
2020-06-06, 1399/03/17

Ethics committee reference number
IR.HUMS.REC.1399.165

Health conditions studied

1

Description of health condition studied
Laboratory confirmed COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Respiratory rate
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
Pulse oximeter

2

Description
Oxygen saturation state and arterial oxygen partial pressure ratio
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
Pulse oximeter

3

Description
Lung infiltration status
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
chest x-ray

4

Description
LDH level's
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
pathobiology laboratory

5

Description
CRP level's
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
pathobiology laboratory

6

Description
Lymphocyte count
Timepoint
At the beginning of the study (before the intervention) and day 5 after the intervention
Method of measurement
pathobiology laboratory

7

Description
Endogenous erythropoietin level's
Timepoint
Beginning of study (before intervention)
Method of measurement
Pathobiology laboratory

8

Description
Patients' blood pressure
Timepoint
At the beginning of the study (before the intervention), during the intervention (5-day erythropoietin administration)
Method of measurement
Sphygmomanometer

Secondary outcomes

1

Description
Patients' blood hemoglobin levels
Timepoint
Start of study (before the intervention), day 5 after the intervention and 2 to 4 weeks after the intervention
Method of measurement
Pathobiology laboratory

Intervention groups

1

Description
Intervention group: Group A.: The standard drug treatment is based on the treatment protocols of the National Committee of COVID-19 and erythropoietin recombinant (EPREX Manufactured by Johnson and Johnson Pharmaceutical Company) 300 units / Kg or 4000IU as subcutaneous injection five times a day for 5 days and simultaneously Enoxaparin 1mg / kg SQ daily is also taken to prevent thrombosis. Patients' blood pressure, along with other vital signs, is checked regularly and at regular intervals. Standard drug treatment according to the treatment protocols of the National Committee for COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate:• Hydroxychloroquine sulfate tablets 200 mg or chloroquine phosphate tablets 250 mg (equivalent to 150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician:• Caltrate tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days• Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days
Category

Treatment - Drugs

2

Description
Control group: Group B: The standard drug treatment is based on the treatment protocols of the National Committee for COVID-19 and the placebo(distilled water) is given as a subcutaneous injection five times a day for 5 days. Standard drug treatment according to the treatment protocols of the National Committee for COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate:• Hydroxychloroquine sulfate tablets 200 mg or chloroquine phosphate tablets 250 mg (equivalent to 150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician:• Caltrate tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days• Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohammadi Hospital

Full name of responsible person
Dr. Mehdi Hassaniazad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dariush Hooshyar

Position
Student of Medicine

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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