Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of Dexamethasone treatment in high-risk covid19 patients in Qom

Protocol summary

Study aim
Determination of dexamethasone treatment in COVID 19 patients in Qom province

Design
A clinical trial with a control group, with parallel groups, without blinding, phase 3 on 60 patients. It was used for randomization through blocking.

Settings and conduct
This study determined dexamethasone treatment in COVID 19 patients in Qom province, a randomized clinical trial without blindness.

Participants/Inclusion and exclusion criteria
Study entry criteria: 1- <70 adults (defined as .18 years 2- Laboratory confirmation of Covid19 b infection 3. Covid19's new organ dysfunction. Criteria for leaving the study: Sensitivity or sensitivity to Lopinavir / Ritonavir or recombinant IFN-β1b 2- ALT above 5 times normal 3. Use of drugs that are contraindicated with lopinavir / ritonavir and should not be substituted or discontinued during the study period. 4- Pregnancy 5. Known HIV infection 6. Uncontrolled diabetes 7. Vulnerable groups, such as the mentally disabled, emergency patients, or prisoners, are excluded from the study.

Intervention groups
In this study, clinical trials of researchers from hospitalized patients in Beheshti and Forghani hospitals Having COVID 19 That by receiving oxygen by The method of Reserve bag Oxygen saturation percentage should be less than 94%, provided that they have entry criteria, in two groups of 30 people selected as control and intervention, And randomly enter the blockade allocation into one of two treatment groups.In addition to receiving treatment for the Ministry of Health's protocol, the intervention group was treated with dexamethasone after obtaining informed consent, and the second group was treated only with the Ministry of Health's protocol. And both groups will be analyzed.

Main outcome variables
Initial outcome (death within 30 days after hospitalization) Secondary effect (mortality over the next year)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160118026097N4**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **retrospective**

Last update: **2020-09-13, 1399/06/23**
Update count: **0**

Registration date
2020-09-13, 1399/06/23

Registrant information

Name
Jamshid Vafaeemanesh

Name of organization / entity
Qom University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-29, 1399/01/10

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Dexamethasone treatment in high-risk covid19 patients in Qom

Public title

The effect of dexamethasone in the treatment of high-risk covid19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years Laboratory confirmation of Covid19 infection with reverse transcription polymerase chain reaction (RT-PCR) from any diagnostic sampling source The new organ dysfunction, which is related to Covid19, includes: Hypoxia requires supplemental oxygen to maintain oxygen saturation> 90%. hypotension (systolic blood pressure <90 mmHg) or need for vasopressor / inotropic drug.Renal impairment (especially creatinine) 50% of baseline, onset, received based on glomerular filtration film. Reduce the scale of Glasgow 2 or more, Thrombocytopenia (<150,000 platelets per millimeter). Symptoms of gastrointestinal upset requiring hospitalization (eg, severe nausea, vomiting, diarrhea, or abdominal pain

Exclusion criteria:

Sensitivity or sensitivity to Lopinavir / Ritonavir or recombinant IFN-β1b, including toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema or angioedema syndrome. ALT above 5 times normal Use of drugs that are contraindicated with Lupinavir / RitonavirAnd do not replace or stop during the study period, such as CYP3A inhibitors. Pregnancy - Eligible female participants are tested at gestational age before enrolling in a pregnancy study. HIV infection is known to cause concern about the resistance to lepinavir / ritonavir if used in combination with other anti-HIV drugs. Uncontrolled diabetes (Prohibition of prednisolone). According to the 31st National Guide, all vulnerable groups, such as the mentally disabled, emergency patients, or inmates, are excluded from the study.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be performed by a random sampling method, block allocation. In such a way that In this study, 60 patients with corona will be randomly divided into two groups. The selection of groups will be based on the fact that individuals will be assigned to groups based on block randomization. Block size 4 is considered. So we have six blocks of four, ABAB, ABBA, AABB, BAAB BBAA, BABA. The selection of each block will also be random and will be done using dice. For example, if the number 5 comes in the dice roll, the AABB block is considered and Therefore, the first two patients are assigned to treatment A, and the two patients are then assigned to treatment B.The dice will be thrown ten times to complete the allocation of patients to treatment groups. Treatment with dexamethasone and control will also be based on accident (coin toss).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The patient will be visited every one to three months based on treatment needs And other follow-ups will be done by phone.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

shahid beheshti Blv

City

qom

Province

Ghoum

Postal code

3713649373

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.MUQ.REC.1399.085

Health conditions studied

1

Description of health condition studied

COVID19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description
Initial outcome (mortality rate or Recovery within 30 days after hospitalization)
Timepoint
the experiment of RT-PCR In the lower respiratory tracts When entering the study and One week after treatment Repeat every week too Negative sample twice.
Method of measurement
Examining and filling out checklists and performing RT-PCR tests

Secondary outcomes

1

Description
Days without organ support (eg, supplemental O2, mechanical ventilation, dialysis and vasopressors): 28 days 2- RT-PCR examination At the time of admission to the study and one week after treatment and every week to negative sample Twice.3-Body failure assessment scores 4-staying time in ICU A period of one year after discharge. 5 The duration of hospital stay - the period of one year after discharge6-Mechanical ventilation duration - one year after discharge.7-Chest radiographic findings Time interval: first and 28 days later.8-Number of patients with side effects from treatment over a period of 28 days Such as diabetes, hypothyroidism, hyperlipidemia, hypertension, cataracts, glaucoma, cushingoid complications and gastrointestinal and skin complications.9- ICU mortality - a period of one year after discharge. 10-Hospital mortality - a period of one year after discharge.
Timepoint
The patient will be visited every one to three months of treatment based on the need for treatment and other follow-ups will be done by phone.
Method of measurement
In-person examination and telephone follow-up

Intervention groups

1

Description
Intervention group: After obtaining informed consent and a full explanation of the treatment steps to the patient and accompanying regarding the treatment process, In addition to receiving the Ministry of Health's treatment protocol, dexamethasone is treated daily 0/1mg/kg for a week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
beheshti & forqani hopitals in qom
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology of Qom 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
Ghoum University of Medical Sciences
Full name of responsible person
hasan adeli
Position
Associate professor
Latest degree
Subspecialist
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared after people have not been identified
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use of meta-analysis
From where data/document is obtainable
DR Jamshid vafaeemanesh
What processes are involved for a request to access data/document
Correspondence with the responsible author
Comments
does not have