Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of efficacy and safety of colchicine in combination with infliximb compared with infliximb in the treatment of patients with Covidian 19: a randomized clinical trial

Protocol summary

Study aim

Determination of efficacy and safety of colchicine with Infliximab in comparison with Infliximab in the treatment of patients with Covid 19

Design

The study will be open label and random. Block randomization will be used for randomization. The minimum number of patients in each group will be 35. Patients are randomly divided into two groups (9 blocks of 4 in each group) by ABAB (blocks with size 4) blocking method and will be entered by census in patients with inclusion criteria.

Settings and conduct

Group 1: Patients with COVID-19 with inclusion criteria admitted to Firoozgar Hospital will be treated with 1 mg of colchicine (for 7 days) and infliximab (single dose of 300 mg on the first day of treatment) and recommended treatments for COIVD-19. Group 2: patients will receive standard treatment with Infliximab (single dose of 300 mg on the first day).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with the common type of Novel Coronavirus Pneumonia (NCP) (with risk factors including increased pulmonary lesions with or without fever) and critical progression of NCP between the ages of 18 and 85 with increased IL-6 levels Exclusion criteria: 1. Patients participating in other clinical studies 2. Pregnant or lactating women 3. Consumers of immunomodulators to prevent transplant rejection or other cases 4. Sensitivity to any of the medicinal compounds 5. Patients with active pulmonary tuberculosis, specific bacterial and fungal infections; Patients with malignancy

Intervention groups

Group A: Infliximab+ Standard Treatment+ Colchicine
Group B: Infliximab+ Standard Treatment

Main outcome variables

Primary Outcomes: 1. Evaluation of clinical symptoms 2. Evaluation of CT scan changes 3. Evaluation of lymphopenia 4. Evaluation of IL-6 level Secondary Outcomes: 1. Evaluation of TNF-α , Interferon Gamma, CRP, ESR and Ferritin levels 2. Evaluation of drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046854N2**
Registration date: **2021-05-03, 1400/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-03, 1400/02/13**
Update count: **0**

Registration date

2021-05-03, 1400/02/13

Registrant information

Name

Maryam Farasatinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4460 4800

Email address

maryfarasati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-16, 1399/12/26

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of colchicine in combination with infliximb compared with infliximb in the treatment of patients with Covidian 19: a randomized clinical trial

Public title

Colchicine in combination with infliximb compared with infliximb in the treatment of patients with Covidian 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the common type of Novel Coronavirus Pneumonia (NCP) (at high risk) and other severe cases of newly diagnosed coronavirus pneumonia between the ages of 18 and 85 with an increase in IL-6 levels if the patient or his or her judge agrees to participate. Study and after signing the informed consent entered the study. Definition of clinical cases of the novel Coronavirus Pneumonia (NCP) :. 1. Specifications with NCP (with serious risk factors): Contains lung lesions based on common clinical signs of NCP with or without fever. 2. NCP critical patient.

Exclusion criteria:

1. Patients participating in other clinical studies 2. Pregnant or lactating women; 3. Patients receiving immunomodulatory drugs to prevent graft rejection or other cases; 4. Allergy to any of the drug compounds; 5. Patients with active pulmonary tuberculosis, with specific bacterial and fungal infections; Patients with malignancy

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by block randomization with size of 4. Random number table is used as a randomization tool.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-03-16, 1399/12/26

Ethics committee reference number

IR.IUMS.REC.1399.1454

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

Evaluation of clinical symptoms

Timepoint

Before the intervention and daily during the intervention

Method of measurement

Clinical evaluation of the patient/ Questionnaire

2

Description

Evaluation of pulmonary CT scan changes

Timepoint

Before the intervention and every other day during the intervention

Method of measurement

Pulmonary CT scan

Secondary outcomes

1

Description
Evaluation of TNF-Alfa level trend
Timepoint
Before receiving the drug and one week after treatment
Method of measurement
Elisa Test

2

Description
Evaluation of Interferon Gamma level trend
Timepoint
Before receiving the drug and one week after treatment
Method of measurement
Elisa test

3

Description
Evaluation of CRP level trend
Timepoint
Before receiving the drug and one week after treatment
Method of measurement
CRP Test Quantitative/Blood sample

4

Description
Evaluation of ESR level trend
Timepoint
Before receiving the drug and one week after treatment
Method of measurement
Westergren method/ Blood sample

5

Description
Evaluation of Ferritin level trend
Timepoint
Before receiving the drug and one week after treatment
Method of measurement
Electrochemiluminescence immunoassay

6

Description
Evaluation of Adverse Drug Reaction
Timepoint
Daily from the beginning of the intervention
Method of measurement
Naranjo Adverse Drug Reaction Probability Questionnaire

7

Description
Evaluation of IL-6 inflammatory factor level trends
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Elisa test

8

Description
Evaluation of lymphopenia
Timepoint
Before the intervention and daily during the intervention
Method of measurement
CBC diff test

Intervention groups

1

Description
Intervention group: Infliximab+ Standard Treatment+ Colchicine: Patients in this group were treated concomitantly with 1 mg of colchicine (for 7 days) with infliximab (single dose of 300 mg on the first day of treatment) and recommended treatments for COIVD-19 (standard treatment provided in the latest national guideline to COVID-19 disease).Currently the standard national guideline includes: 200 mg hydroxychloroquine or 250 mg chloroquine (two tablets every 12 hours on the first day and one tablet every 12 hours for at least 7 days and up to 14 days) + kaletra (lupinavir / ritonavir) 200/50 mg every 12 hours 2 tablets for a minimum of 7 days and a maximum of 14 days or tablets (Atazanavir / Ritonavir) 300/100 mg/day with food for a minimum of 7 days and a maximum of 14 days.
Category
Treatment - Drugs

2

Description
Control group: Infliximab+ Standard Treatment: In addition to standard treatment, patients in this group will receive infliximab (single dose of 300 mg on the first day).Currently the standard national guideline includes: 200 mg hydroxychloroquine or 250 mg chloroquine (two tablets every 12 hours on the first day and one tablet every 12 hours for at least 7 days and up to 14 days) + kaletra (lupinavir / ritonavir) 200/50 mg every 12 hours 2 tablets for a minimum of 7 days and a maximum of 14 days or tablets (Atazanavir / Ritonavir) 300/100 mg/day with food for a minimum of 7 days and a maximum of 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Maryam Farasatinasab
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City

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Sponsors / Funding sources

1

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Name of organization / entity
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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
Iran University of Medical Sciences
Proportion provided by this source
1
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
Iran University of Medical Sciences
Full name of responsible person
Maryam Farasatinasab
Position
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Person responsible for updating data

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Some of the information including the primary or secondary outcome can be shared.

When the data will become available and for how long

8 months after the end of the study

To whom data/document is available

Medical specialists

Under which criteria data/document could be used

In case of a written request to the study authorities and while preserving the copyright, part of the information including the primary or secondary outcome will be made available to the applicants.

From where data/document is obtainable

Maryam Farasatinasab, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences. Email: maryfarasati@gmail.com

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

At the formal request to the person in charge of study

Comments