# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jul 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

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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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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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research-m@iums.ac.ir
**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**
Assistant Professor of Clinical Pharmacy
**Latest degree**
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**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

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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**