# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluation of therapeutic effect of baricitinib in patients with severe pneumonia requiring non-invasive ventilation induced to Covid 19

### Protocol summary

**Study aim**

Evaluation of therapeutic effect of baricitinib with control in patients with severe pneumonia requiring non-invasive ventilation induced by Covid 19

**Design**

A clinical trial, with a control group; single-blind, sample size 15; randomized with random sequence generation software

**Settings and conduct**

location: Ghaem hospital of Mashhad. All patients will receive standard Covid 19 treatment consisting of Remsidior / Anticoagulant / Aspirin / Corticosteroids / Vitamins C and D, Zinc and Serum therapy if needed, an interleukin-6 inhibitor. divided into two equal groups, one group oral baricitinib 4 mg daily next group placebo will be used. based on the order of entry of eligible participants to the study, one of the envelopes is opened in order and the assigned group of the participant is revealed. The parameters mentioned earlier and mortality in 30 days, 60 days, and 90 days / the rate of ICU infections, the need for antibiotics, and the time of hospital discharge are also compared in the two groups.

**Participants/Inclusion and exclusion criteria**

Patients with severe covid-19, who diagnosed by PCR or radiological criteria with clinical symptoms of covid-19 with history of respiratory symptoms from one week ago, who were diagnosed with acute respiratory failure and required non-invasive ventilation to maintain O2 saturaion above 85% in ICU, were entered in study.

**Intervention groups**

one group, standard treatment of covid plus oral baricitinib (4 mg daily) and next group recieve standard treatment of covid .

**Main outcome variables**

Mortality rate, APACHEII score, number of days of ventilator dependence, serum level of CRP, serum level of neutrophils and lymphocytes, serum level of lactate dehydrogenase enzyme, d-dimer gasometry, procalcitonin, liver and Kidney and Blood tests, occurance of respiratory distress and sepsis, demographic information, amount and type of drugs used during the study

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220508054780N1**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**
Update count: **0**

**Registration date**

2022-09-16, 1401/06/25

**Registrant information**

**Name**

Benyamin Fazli

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3802 2711

**Email address**

fazlib@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-10-02, 1401/07/10

**Expected recruitment end date**

2022-12-31, 1401/10/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of therapeutic effect of baricitinib in patients with severe pneumonia requiring non-invasive ventilation induced to Covid 19

**Public title**

Evaluation of therapeutic effect of baricitinib in patients with severe pneumonia requiring non-invasive ventilation induced to Covid 19

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with severe covid 19 who fullfill PCR or radiological criteria for covid 19 clinical symptoms History of respiratory symptoms from one week before, with a diagnosis of acute respiratory failure Requires non-invasive ventilation to maintain O2 saturation above 85% in ICU

**Exclusion criteria:**

Increased liver enzymes and renal failure Bacterial, fungal and viral infections Bone marrow suppression and decrease in leukocytes

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization with a table of random numbers using www.sealedenvelope.com A set of random numbers is generated and placed in a table. First, determine the direction of reading the numbers in the table. A numerical group is assigned to each intervention and control group. Then we choose a random number and move in the specified direction and record the numbers and assign them to different groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Allocation concealment by sealed envelopes. some envelopes will be prepared, and each of the random sequences will be recorded on a card, and the cards will be placed inside the envelopes. To preserve the random sequence, the pass number will be written on the outer surface of the envelopes in the same way. Finally, the envelopes will be sealed and placed inside the boxes. At the time of registration of the companies, according to the order of entry of qualified companies into the study, one of the envelopes will be opened, and the allocated group of that participant will be revealed. Allocated groups consist of an intervention group and a placebo group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Mashhad University of Medical Sciences

**Street address**

Shahid Fakouri Blvd – Mashhad - Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2022-04-12, 1401/01/23

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.147

## Health conditions studied

### 1

**Description of health condition studied**

Acute viral infection caused by the corona virus (COVID-19)

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

**Description**

The mortality rate of patients with acute respiratory infection of the coronavirus who admitted in ICU

**Timepoint**

30, 60 and 90 days

**Method of measurement**

observation of the number of dead patients

### 2

**Description**

Score of disease severity questionnaire (APACHEII)

**Timepoint**

30, 60 and 90 days

**Method of measurement**

APACHEII questionnaire

**3**

**Description**

Number of days that a patient is on ventilator

**Timepoint**

30, 60 and 90 days

**Method of measurement**

observation of the number of days the patient is on ventilator.

**4**

**Description**

Incidence of sepsis

**Timepoint**

30, 60 and 90 days

**Method of measurement**

Evaluation of the patient's clinical symptoms and laboratory findings.

**5**

**Description**

Incidence of respiratory distress

**Timepoint**

30, 60 and 90 days

**Method of measurement**

Clinical evaluation of respiratory distress in patients.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: the group of patients with severe pneumonia requiring non-invasive ventilation due to covid-19. this group will be treated with standard covid treatment including remdesivir, anticoagulant, aspirin, cortone,vitamin C and D and zinc and serum therapy if needed and tocilozumab plus oral baricitinib at a dose of 4 mg daily، Sorin Salamat Sabz production ،

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients with severe pneumonia require non-invasive ventilation due to Covid 19. this group will be treated with standard covid treatment including remsidior, anticoagulant, aspirin, cortone,vitamin C and D and zinc and serum therapy if needed and infusion of injectable tocilizumab (Actemra) at a dose of 400 mg as a single dose.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ghaem Hospital of Mashhad

**Full name of responsible person**

Dr. Benyamin Fazli

**Street address**

Ahmadabad Boulevard

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fazlib@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Benyamin Fazli

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vcreseach@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Benyamin Fazli
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for updating data

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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