

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation the efficacy of Tumor Necrosis Factor alpha inhibitor in COVID-19 outcomes: a prospective clinical trial study.

#### Protocol summary

##### Study aim

Evaluation the efficacy of Anti- TNF on COVID-19

##### Design

In this simple clinical trial study, 80 patients with inclusion criteria will be selected by the non-randomized selection and divided in two balance group. The two groups will be matched as the same gender, age and background disorders.

##### Settings and conduct

The blood glucose, CBC, ESR, CRP, LFT will be checked for all patients according to hospital protocols. The LFT and blood glucose will be checked again one week and 10 days after injection of medicine and placebo. The radiologic evaluation with CT scan will be done in all patients according to the hospital protocols. The second CT one week later, will depend on the patient's situation. The data will be documented in the anonymous questionnaire with special codes for each person.

##### Participants/Inclusion and exclusion criteria

Confirmed the COVID-19 disease with one or more of these: fever, dry cough, dyspnea and one or more of below: positive SARS-COV2 PCR; characteristic changes of SARS-COV2 in chest CT; age>18 years old; signing inform consent; no history of diabet , heart failure, TB and the other chronic disease. Exclusion criteria: administration of corticosteroids pulses and/or IVIG in the disease process or one month after anti-TNF prescription; unwillingness of involved patients.

##### Intervention groups

Altebrel 50 mg subcutaneously in 2 dose in one week.

##### Main outcome variables

Improvement of pulmonary manifestations and the duration of it;Improvement the radiologic parameters; necessity to ICU admission; duration the ICU admission; duration the hospitalization; the mortality; the time of mortality; the three months outcomes: complete improvement; improvement with transient complication; improvement with persistent complication; death

#### General information

##### Reason for update

because of difficulties in production of placebo, the control group have not taken placebo.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200312046749N1**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-12, 1399/01/24**

Update count: **1**

##### Registration date

2020-03-28, 1399/01/09

##### Registrant information

##### Name

Raheleh Assari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6694 8443

##### Email address

r1assari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-27, 1399/01/08

##### Expected recruitment end date

2020-09-29, 1399/07/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation the efficacy of Tumor Necrosis Factor alpha inhibitor in COVID-19 outcomes: a prospective clinical trial study.

## Public title

Efficacy of Tumor Necrosis Factor alpha inhibitor in COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Confirmed the COVID-19 disease with one or more of these: fever, dry cough, dyspnea and one or more of below: positive SARS-COV2 PCR • Characteristic changes of SARS-COV2 in chest CT scan such as bilateral ground glass opacity in bases of the lungs ( confirmation with the radiologist) Age>18 years old Signing inform consent from the patient or patient s accompaniment No manifestations of bacterial infection No history of rheumatologic disorders No history of cancer for the last 1 year.No history of immunodeficiency (primary or acquired) No manifestations, history and radiologic parameters according to active or latent TB No diabetes or autoimmune hepatitis No uveitis No history of immunosuppressive treatment in the last 6 months No history of growth hormone, Testosterone and any Anabolic steroids in the last one month No history of Corticosteroid therapy (>30 mg/m2) for > 5 days in the last one month No history of Corticosteroid pulses or IVIG treatments for last one month No history of Biologics treatment for the last 6 months

### Exclusion criteria:

Administration of corticosteroids pulses and/or IVIG in the disease process or one month after anti-TNF prescription. Unwillingness of involved patients to continue this research.

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Qods St., Keshavarz Blvd., Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2020-03-24, 1399/01/05

#### Ethics committee reference number

IR.TUMS.VCR.REC.1399.034

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19

## Primary outcomes

### 1

#### Description

Improvement of pulmonary manifestations and the duration.

#### Timepoint

One week, two weeks and 6 months after

#### Method of measurement

physical examination, laboratory data and CT scan

### 2

#### Description

Improvement the radiologic parameters.

#### Timepoint

after 7-10 days

#### Method of measurement

computed tomography

### 3

#### Description

Necessity and Duration to ICU admission and hospitalization

#### Timepoint

One to two weeks later

#### Method of measurement

Questionnaire

#### 4

**Description**

Mortality

**Timepoint**

One month later

**Method of measurement**

Number

#### 5

**Description**

The three months outcomes: complete improvement; improvement with transient complication; improvement with persistent complication

**Timepoint**

After three months

**Method of measurement**

Physical examination and history

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group: altebrel 50mg by aryogen company subcutaneously in two dose with 2-3 days duration in one week.

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: In control group, supportive care and protocol without any injection

**Category**

Rehabilitation

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Raheleh Assari

**Street address**

Imam Khomeini Hospital, Bagherkhan street

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r1assari@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

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No.226,Qods St, Keshavarz Blvd, Tehran,Iran.

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vcr@tums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

vice chancellor for research

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Industry

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Vahid Ziaee

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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Markaz Tebi Atfal hospital, Dr. Gharib street

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**Other areas of specialty/work**

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**Postal code**

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**Phone**

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**Email**

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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**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Study protocol

**When the data will become available and for how long**

After finished sampling and data analysis

**To whom data/document is available**

The researchers in university

**Under which criteria data/document could be used**

Help in managing of patients

**From where data/document is obtainable**

The principal investigator

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

Contact with the chief

**Comments**