

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

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Imam Khomeini Hospital, Bagherkhan street

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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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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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Latest degree

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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