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 patient̀ 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

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Iran (Islamic Republic of)

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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 grass opacity in bases of the lungs (confirmation with the radiologist) Age>18 years old Signing inform consent from the patient or patient̀ 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

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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, labratory 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 with2-3 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
professor
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