

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2020

Evaluation of the effect of Tocilizumab on outcomes of the severe COVID-19, determining indications within the paradigm of host-directed therapy

Protocol summary

Study aim

Evaluation of the effect of Tocilizumab on outcomes of the severe COVID-19 patients

Design

The patients become divided in two groups by using block randomization. One group receive tocilizumab (8mg/kg - single dose) and the other receive multi drug standard protocol.

Settings and conduct

Patient with severe corona virus infection in intensive care unit (ICU) in Markazi province hospitals are selected. They become divided in two groups by using block randomization. One group receives tocilizumab (8mg /kg, single dose) and the other receives multi drug standard protocol.

Participants/Inclusion and exclusion criteria

Study entry requirements: covid-19 disease confirmed by chest ct and PCR no pregnancy no breastfeeding negative PPD no bacterial pneumonia (negative sputum and urine culture) don't use of atorvastatin, alprazolam, amlodipine, MTX, hydroxychloroquine Conditions for not entering the study: opposite above conditions

Intervention groups

Patient with severe corona virus infection in intensive care unit (ICU) in Markazi province hospitals are selected. They divided in two groups. One group receive tocilizumab and the other receive multi drug standard protocol.

Main outcome variables

If the drug efficacy become approved, it can promote clinical symptoms, decrease mortality and admission time in ICU , shorten the clearance time of virus , prevention of acute kidney injury and heart failure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047383N1**

Registration date: **2020-05-15, 1399/02/26**

Registration timing: **prospective**

Last update: **2020-05-15, 1399/02/26**

Update count: **0**

Registration date

2020-05-15, 1399/02/26

Registrant information

Name

Zahra sadat Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3457 0202

Email address

zahra.mousavi.1995@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Tocilizumab on outcomes of

the severe COVID-19, determining indications within the paradigm of host-directed therapy

Public title

Evaluation of the effect of Tocilizumab on outcomes of the severe COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 disease confirmed by chest ct and PCR No pregnancy No breastfeeding Negative PPD No bacterial pneumonia (negative sputum and urine culture) Not use of atorvastatin , alprazolam , amlodipine , MTX , hydroxychloroquine , Informed consent

Exclusion criteria:

Disapproval of covid-19 disease by chest computed tomography and PCR Positive PPD Bacterial pneumonia (negative sputum and urine culture) Pregnancy Breastfeeding Use of atorvastatin , alprazolam , amlodipine , MTX , hydroxychloroquine by the patient Lack of Informed consent

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Statistical software using block randomization method

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, the person in charge of data collection and analysis are unaware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran National Committee for Ethics in Biomedical Research

Street address

Arak, Vali-e-Asr Sqr, Vali-e-Asr hospital

City

Arak

Province

Markazi

Postal code

1234567890

Approval date

2020-05-11, 1399/02/22

Ethics committee reference number

IR.ARAKMU.REC.1399.030

Health conditions studied**1****Description of health condition studied**

covid-19 disease

ICD-10 code

U07.1

ICD-10 code description

covid-19 disease

Primary outcomes**1****Description**

Investigation of mortality rate of COVID-19 patients

Timepoint

After treatment

Method of measurement

Situation of the patient's life

Secondary outcomes**1****Description**

The average number of hospitalization days for COVID-19 patients

Timepoint

End of treatment

Method of measurement

Day

2**Description**

Average platelets count

Timepoint

Before and after treatment

Method of measurement

Complete Blood Count (CBC) test

3**Description**

Average percentage of oxygen saturation

Timepoint

Every 12 hours

Method of measurement

Puls oximeter

Intervention groups**1****Description**

Intervention group: Take tocilizumab. This group is given a dose of 8 mg per kilogram of body weight tocilizumab up to a maximum dose of 800 mg. If the symptoms worsen or do not improve, another dose is injected. If side effects occur, the complication is recorded and then the patient is removed from the study.

Category

Treatment - Drugs

2**Description**

Control group: Receive standard multi drug protocol.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr. Mohammadreza Bozorgmanesh

Street address

Imam khomeini street, Vali-e-Asr Sqr, Vali-e-Asr hospital

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mhmmdrz_bzrgmsh@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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Sardasht road, arak medical university

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

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Bozorgmanesh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

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Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahrasadat Mousavi

Position

General practitioner

Latest degree

Medical doctor

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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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The findings will be submitted a related journal for peer review and possible publication

When the data will become available and for how long

In less than a year

To whom data/document is available

Findings are supposed to be published. Data will be available upon the request from the corresponding author

Under which criteria data/document could be used

After publication upon the request from the corresponding author for meta analysis where a full right to the authorship is preserved

From where data/document is obtainable

Upon the request from the corresponding author

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

Describe the design of the research where the data is supposed to be available. We will be asking a full access to the whole data and will be participating in the analysis and interpretation and publication of the study

Comments