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 CIVID-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
City
Arak
Province
Markazi
Postal code
1234567890
Phone
+98 86 3223 1350
Email
mhmmdrz_bzrgmnsh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Alireza Kamali
Street address
Sardasht road, arak medical university
City
arak
Province
Markazi
Postal code
76589-38481
Phone
+98 86 3223 1350
Email
alikamaliir@yahoo.com
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
Street address
Vali-e-Asr Sqr, Vali-e-Asr Hospital
City
Arak
Province
Markazi
Postal code
1234567890
Phone
+98 86 3223 1350
Email
mhmmdrz_bzrgmnsh@yahoo.com

Person responsible for scientific 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

Street address
Vali-e-Asr Sqr, Vali-e-Asr Hospital

City
Arak

Province
Markazi

Postal code
1234567890

Phone
+98 912 528 0241+98 86 3223 1350

Email
mhmmdrz_bzrgmnsh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Zahrasadat Mousavi

Position
General practitionor

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Sardasht Road, Arak Medical University, Medicine College

City
Arak

Province
Markazi

Postal code
76589-38481

Phone
+98 918 433 7401

Email
zahra.mosavi.1995@gmail.com

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