Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

Evaluation of Safety and efficacy of anakinra utilization in COVID-19, a randomized controlled clinical trial

Protocol summary

Study aim
Evaluation the safety and efficacy of Anakinra (Persisgen, Iran) in treatment of COVID-19

Design
Phases 3 randomized, parallel design clinical trial on 30 COVID-19 patients

Settings and conduct
this clinical trial will be conducted in immam hossein medical center affiliated to shahid beheshti university of medical sciences on COVID-19 patients. in this study patients will receive anakinra (perkinra, persisgen, Iran) by the dose of 100 mg once daily by intravenous injection as and adjunctive treatment to antiviral medication based on latest national protocol for treatment of COVID-19

Participants/Inclusion and exclusion criteria
All patients with confirmed SARS-CoV-2 infection who have the ability to understand and desire to sign a form of informed consent to participate in the study with the age of 18 years or more with the PaO2/FiO2 of 300 or less. all patients who have active infections or immunodeficiency and received attenuated vaccine will exclude from the study.

Intervention groups
Intervention group: receiving 100mg Perkinra (anakinra, persisgen, iran) once daily as an adjunctive treatment to standard antiviral regimen Control: Treatment based on last national protocol for treatment of COVID-19

Main outcome variables
1. no need to be hospitalized 2. hospitalization without receiving oxygen therapy 3. hospitalization with receiving oxygen therapy 4. hospitalization with receiving non-invasive ventilation or high flow rate oxygen delivery system 5. hospitalization with receiving invasive ventialtion or extra-corporeal membrane oxygenation 6. death

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120703010178N20**
Registration date: **2020-06-13, 1399/03/24**
Registration timing: **prospective**

Last update: **2020-06-13, 1399/03/24**
Update count: **0**

Registration date
2020-06-13, 1399/03/24

Registrant information
Name
Mohammad Sistanizad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8820 0087
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2020-09-21, 1399/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of Safety and efficacy of anakinra utilization in COVID-19, a randomized controlled clinical trial

Public title
effect of anakinra in treatment of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 years or more Elevated C-reactive protein levels Fever or cough or dyspnea SpO2 of 93% or less Confirmed SARS-CoV-2 infection by rt-PCR or radiology PaO2/FiO2 of 300 or less Ability to understand and desire to sign a form of informed consent to participate in the study
Exclusion criteria:
Positive PPD test Active Hepatitis B or C infection, Positive HBV antigen or HCV antigen or HIV infection Thrombocytopenia (platelet count of 150000 per micL) Leukopenia (white blood cells of 3.6*10^9) Anemia (hemoglobin of 7.5 g/dL) Elevated liver transaminases of 2 fold or more Active infection based on cultures (not received intravenous antibiotics in previous 8 weeks or oral antibiotics in previous 2 weeks) history of malignancy in previous 5 years based on pathology and radiological data history of anakinra, canakinumab or any interleukin-1 inhibitors administration History of receiving of attenuated vaccine in last 2 weeks or during the study hypersensitivity to any component of the medication
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation sequence will computer generate and consist of series of group number (either 1 = A or 2 = B) for each consecutive patient. Block randomization method will use and each block will be consist of 10 patients. Each block includes 5 patients who will receive Anakinra and 5 patients from control group
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
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2020-05-31, 1399/03/11
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.051

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
No need for hospitalization
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

2

Description
Hospitalization without need for oxygenation therapy
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

3

Description
Hospitalization with oxygen therapy
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

4

Description
Hospitalization with receiving non-invasive ventilation or high flow oxygen cannula
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

5

Description
Hospitalization with receiving mechanical ventilation or extra-corporeal membrane oxygenation
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

6

Description
Death
Timepoint
During first 14 days or hospitalization period
Method of measurement
Based on clinical status

Secondary outcomes

1

Description
time for improvement in oxygenation
Timepoint
During 14 days of treatment or discharge time
Method of measurement
pulse oxymeter

2

Description
Mean oxygen delivery
Timepoint
During 14 days of treatment or discharge time
Method of measurement
PaO2/FiO2 ratio

3

Description
number of days with hypoxemia
Timepoint
During 14 days of treatment or discharge time
Method of measurement
pulse oxymetery

4

Description
Time of fever resolution for 48hr or more
Timepoint
During 14 days of treatment or discharge time
Method of measurement
Thermometer

5

Description
Intensive care unit admission time
Timepoint
Hospitalization duration
Method of measurement
Clinical status

6

Description
Rate of secondary fungal or bacterial infections
Timepoint
hospitalization duration
Method of measurement
Laboratory data and clinical status

7

Description
Radiologic severity index
Timepoint
Day 1, 7, 14 or discharge
Method of measurement
Computed tomography

8

Description
C-reactive protein
Timepoint
2 times weekly
Method of measurement
Serum level

9

Description
Interleukin-1 beta serum level
Timepoint
Day 1, 2, 14
Method of measurement
Elisa test

Intervention groups

1

Description
Intervention group: After eligibility assessment of the patient and enrollment patients will be randomly assign to receive anakinra 100mg intravenous daily for 14 days as an adjunctive treatment to the latest recommended pharmacotherapy of national guideline for treatment of COVID-19. the medication will be administered intravenously by a trained staff.
Category
Treatment - Drugs

2

Description
Control group: After eligibility assessment of the patient and enrollment patients will be randomly assign to the control group. patients in control group will receive medical treatment of COVID-19 based on latest national protocol only.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Immam Hossein Hospital
Full name of responsible person
Amir Behnam Kharazmi
Street address
Madani Ave, Tehran, Iran
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1617763141
Phone
+98 21 7755 7069
Email
Drkharazmi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Persisgen Par Pharmaceutical Company
Full name of responsible person
Amir Hossein Karagah
Street address
No. 125, 22nd km of Tehran-Karaj Makhsous Road, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1399114913
Phone
+98 21 4607 4876
Email
Info@persisgen.com
Web page address
Https://persisgen.com/
Grant name
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Persisgen Par Pharmaceutical Company
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associated Professor
Latest degree
Specialist
Other areas of specialty/work
Clinical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Omid Moradi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

clinical pharmacy

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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

No - There is not 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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Primary and secondary outcome data after making unrecognizable will be released

When the data will become available and for how long

6 months after publishing the results of primary outcome

To whom data/document is available

Any researchers will have access to the data after allowance of corresponding author

Under which criteria data/document could be used

Performing any analysis to any data resulted form this study will be allowed only with the permission of corresponding author

From where data/document is obtainable

Correspondance

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

After requesting for data, correspondence will check the authorization and then they will be informed about it

Comments