

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 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 ventiation 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)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

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 oxymetry

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

City

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Province

Tehran

Postal code

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

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 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 from 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