

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 2021

Evaluating the safety and efficacy of allogeneic NK cells on COVID-19 induced pneumonia, double blind, randomized clinical trial

Protocol summary

Study aim

Study of safety and efficacy of allogeneic NK cells in patients with COVID-19 pneumonia

Design

Randomized double-blind clinical trial (phase 1-2) with control group and parallel group design. The random function of the Excel software is used for randomization.

Settings and conduct

This study is carried out in the infectious ward of Imam Khomeini hospital in Tehran. The patients are divided into distinct groups according to the random algorithm. The study will be double blind. A code is considered for each person and placed in an envelope, or an electronic file then presented to the physicians and the nurses. Elsewhere, it is clear that the code is related to the drug or placebo. Only if the person's health is compromised the code will be broken prematurely.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all of patients with COVID-19 pneumonia that is confirmed by chest radiography or computed tomography with real time PCR. Exclusion criteria: Pregnancy or breastfeeding; Known HIV, HBV or HCV infection; Patients with malignant tumor, other serious systemic diseases or psychosis; Patients who are participating in other clinical trials

Intervention groups

Patients will be included in seven groups and will receive different doses of NK cells (with increasing trend). Treatment group A: 0.1×10^7 cells per kilogram patient weight. Treatment group B: 0.5×10^7 cells per kilogram patient weight. Treatment group C: 1×10^7 cells per kilogram patient weight. Treatment group D: 1.5×10^7 cells per kilogram patient weight. Treatment group E: 2×10^7 cells per kilogram patient weight. Treatment group F: placebo. Group G: control

Main outcome variables

Fever; Cough; Skin disorders; Number of breathes per minute; Pulmonary volume; Pulmonary capacity; Airway resistance; Lung elasticity; Chest pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200417047113N1**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **prospective**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

Sahar Shojaei

Name of organization / entity

Middle East Gene Therapy project

Country

Iran (Islamic Republic of)

Phone

+98 21 4478 7327

Email address

shojaeisahar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-27, 1399/02/08

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the safety and efficacy of allogeneic NK cells on COVID-19 induced pneumonia, double blind, randomized clinical trial

Public title

Effect of NK cell therapy in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All COVID-19 patients confirmed by CT scan with positive RT-PCR

Exclusion criteria:

Pregnancy or breastfeeding Known HIV, HBV or HCV infection Patients with malignant tumor, other serious systemic diseases and psychosis Diabetic patients Patients who are participating in other clinical trials

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to one of the 7 study groups using random number table and receive intervention from the same group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study all participants will be blinded, including COVID-19 patients, the principal investigator who is an infectious disease specialist, as well as all physicians, nurses and treatment teams, as well as data collection officials and those who assessed the consequences after interventions. The patients in the study are divided into distinct groups according to the random algorithm. A code is considered for each person and placed in an envelope, or a electronic file then presented to the physicians and the nurses. Elsewhere, it is clear that the code is related to the drug or placebo. When prescribing, the patient's code must be matched with the code on the cell product by the responsible physician and nurse. Only if the person's health is compromised, the code will be broken prematurely. This code also is unique for each individual, and if a code is broken, physician and researcher will not know the other patient's codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No. 226, Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2020-12-21, 1399/10/01

Ethics committee reference number

IR.TUMS.VCR.REC.1399.069

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

2

Description of health condition studied

COVID-19

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

3

Description of health condition studied

Viral pneumonia

ICD-10 code

J12.8

ICD-10 code description

Other viral pneumonia

Primary outcomes

1

Description

Fever

Timepoint

Days 1, 3, 7, 14, and 28

Method of measurement

Thermometer

2**Description**

Number of breathes per minute

Timepoint

Days 1, 3, 7, 14, and 28 after cell injection.

Method of measurement

Records of the number of breaths in a minute by Nurse in 3 consecutive minutes

3**Description**

Pulmonary volume

Timepoint

Days 7 and 14

Method of measurement

Spirometer

4**Description**

Pulmonary capacity

Timepoint

Days 7 and 14

Method of measurement

Spirometer

5**Description**

Airway resistance

Timepoint

Days 7 and 14

Method of measurement

Spirometer

6**Description**

Lung elasticity

Timepoint

Days 7 and 14

Method of measurement

Spirometer

7**Description**

Chest pressure

Timepoint

Days 7 and 14

Method of measurement

Spirometer

8**Description**

Cough

Timepoint

Days 1, 3, 7, 14, and 28 after cell injection.

Method of measurement

Records in questionnaire by nurse according to defined qualitative criteria

9**Description**

Skin disorders

Timepoint

Days 1, 3, 7, 14, and 28

Method of measurement

Records in questionnaire by nurse according to defined qualitative criteria

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

Lymphopenia

Timepoint

Day 7

Method of measurement

Complete blood count

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

Intervention group 1: treatment group A, 0.1×10^7 NK cells per kilogram of patient weight. The lowest dose of cells will be injected into this treatment cohort. These patients will be examined at intervals 1, 3, 7, 14, 28 after cell injection for safety and efficacy effects.

Category

Treatment - Other

2**Description**

Intervention group 2: treatment group B, 0.5×10^7 NK cells per kilogram of patient weight. The middle dose of the cells will be injected into this treatment cohort. These patients will be examined at intervals 1, 3, 7, 14, 28 after injection for safety and efficacy effects.

Category

Treatment - Other

3**Description**

Intervention group 3: treatment group C, 1×10^7 NK cells per kilogram of patient weight. The middle dose of the cells will be injected into this treatment cohort. These patients will be examined at intervals 1, 3, 7, 14, 28 after injection for safety and efficacy effects.

Category

Treatment - Other

4

Description

Intervention group 4: treatment group D, 1.5 * 107 NK cells per kilogram of patient weight. The middle dose of the cells will be injected into this treatment cohort. These patients will be examined at intervals 1, 3, 7, 14, 28 after injection for safety and efficacy effects.

Category

Treatment - Other

5

Description

Intervention group 5: treatment group E, 2 * 107 NK cells per kilogram of patient weight. The highest dose of cells will be injected into this treatment cohort. These patients will also be examined at intervals of 1, 3, 7, 14, 28 days in terms of safety and effectiveness outcomes.

Category

Treatment - Other

6

Description

Intervention group 6: placebo, in this group, only physiological serum will be injected into patients. These patients will also be examined at intervals of 1, 3, 7, 14, 28 days in terms of safety and effectiveness outcomes.

Category

Placebo

7

Description

Control group: They do not receive any treatment other than common medications. These patients will also be examined at intervals of 1, 3, 7, 14, 28 days in terms of safety and effectiveness outcomes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Minoo Mohraz

Street address

Imam Khomeini hospital, Dr Gharib street., Keshavarz boulevard

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Middle East Gene Therapy corporation

Full name of responsible person

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S.shojaei@megenetherapy.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Middle East Gene Therapy corporation

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

Middle East Gene Therapy Corporation

Full name of responsible person

Sahar Shojaei

Position

Chairman of the Board

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available