Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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 rand 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 a electronic file then presented to the physicians and the nurses. Elsewhere, it is clear that the code is the 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 * 107 cells per kilogram patient weight. Treatment group B: 0.5 * 107 cells per kilogram patient weight. Treatment group C: 1 * 107 cells per kilogram patient weight. Treatment group D: 1.5 * 107 cells per kilogram patient weight. Treatment group E: 2 * 107 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)

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+98 21 4478 7327

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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 possitive 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 * 107 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 * 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

3

Description
Intervention group 3: treatment group C, 1 * 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

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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1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Middle East Gene Therapy corporation
Full name of responsible person
Sahar Shojaei
Street address
Middle East Gene Therapy Co., Pajoohesh boulevard, Hamedani highway, Tehran
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14965161
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+98 21 4478 7327
Email
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
Street address
Middle East Gene Therapy Co., Pajoohesh boulevard, Hamedani highway
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Other areas of specialty/work
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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