

# 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 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:  $0.1 \times 10^7$  cells per kilogram patient weight. Treatment group B:  $0.5 \times 10^7$  cells per kilogram patient weight. Treatment group C:  $1 \times 10^7$  cells per kilogram patient weight. Treatment group D:  $1.5 \times 10^7$  cells per kilogram patient weight. Treatment group E:  $2 \times 10^7$  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<sup>7</sup> 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<sup>7</sup> 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<sup>7</sup> 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 \* 10<sup>7</sup> 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 \* 10<sup>7</sup> 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 0000

**Email**

**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

**City**

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**Province**

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**Postal code**

14965161

**Phone**

+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

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Middle East Gene Therapy Co., Pajoohesh boulevard, Hamedani highway

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S.shojaei@megenetherapy.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Middle East Gene Therapy Corporation  
**Full name of responsible person**  
Sahar Shojaei  
**Position**  
Chairman of the Board  
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**Other areas of specialty/work**  
Medical Biotechnology  
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shojaeisahar@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Middle East Gene Therapy Corporation  
**Full name of responsible person**  
Sahar Shojaei  
**Position**  
Chairman of the Board  
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shojaeisahar@gmail.com

## 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