

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

### Phase I clinical trial using ex vivo-expanded allogeneic donor-derived NK cells in patients with lower respiratory disease (Moderate) caused by COVID-19.

#### Protocol summary

##### Study aim

Determination of the treatment side effects such as fever, rash, changes in blood homeostasis and blood sugar, cardiopulmonary problems after allogeneic Natural Killer Cell (NK cell) infusion in treatment-resistant Coronavirus disease 2019 (COVID-19) patients. • Determining the percentage of lung saturation in computerized tomography (CT)-Scan graphs of patients before and after allogeneic NK cell infusion in patients with resistant COVID-19

##### Design

8 patients in the case group and 6 patients in the control group are nominated for cell therapy and vital signs, allergic reactions after injection are monitored until release.

##### Settings and conduct

Intravenous injection of NK cells to patients with COVID-19 related severe pneumonia ( $2 \times 10^6$  cell /kg) in the intensive care unit (ICU) and infusion safety assessment in patients until the release date

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria - pneumonia that is confirmed by chest imaging (glass turbidity in HRCT) - Laboratory Confirmation of Infection (NCP, Novel Coronavirus Pneumonia,) with Reverse chain Polymerase (RT-PCR) - Ordinary transthoracic echocardiogram Exclusion Criteria -A known case of HBV, HIV, HCV -Patients with other serious systemic diseases or malignancies

##### Intervention groups

1. Patients with "treatment-resistant" pneumonia of COVID-19 infection will receive one-dose of NK cell infusion ( $2 \times 10^6$  /Kg). The routine treatments will not be stopped. 2. Control Group: Patients with "treatment-resistant" pneumonia of COVID-19 infection who are aligned with group1 in case of age, body weight, and clinical status. They will not receive cell therapy and the routine treatment would be executed.

#### Main outcome variables

Safety assessment in case of allergic symptoms evaluation such as fever, Heart rate, Pulse rate, artemia cardiac, Respiratory rate, saturation status, and reduction of acute respiratory symptoms

#### General information

##### Reason for update

##### Acronym

NKCTC

##### IRCT registration information

IRCT registration number: **IRCT20200621047859N2**

Registration date: **2020-12-29, 1399/10/09**

Registration timing: **retrospective**

Last update: **2020-12-29, 1399/10/09**

Update count: **0**

##### Registration date

2020-12-29, 1399/10/09

##### Registrant information

##### Name

Ramin Sarrami Forooshani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8879 6003

##### Email address

rsf1351@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2020-12-21, 1399/10/01  
**Actual recruitment start date**  
2020-09-01, 1399/06/11  
**Actual recruitment end date**  
2020-09-08, 1399/06/18  
**Trial completion date**  
2020-12-08, 1399/09/18

**Scientific title**  
Phase I clinical trial using ex vivo-expanded allogeneic donor-derived NK cells in patients with lower respiratory disease (Moderate) caused by COVID-19.

**Public title**  
Immune cell therapy for patients with COVID-19 related pneumonia using allogenic ex vivo NK cells

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Man or woman, aged 18-70 years pneumonia that is confirmed by chest imaging (glass turbidity in High-resolution computed tomography[HRCT]) Laboratory confirmation of infection (NCP, Novel Coronavirus Pneumonia) with reverse polymerase chain reaction (RT-PCR) response from any diagnostic sampling source. Ordinary transthoracic echocardiogram Adequate kidney function, which is estimated based on glomerular filtration rate (CrCl> 60) ml / min or ml per minute / 1.73 square meters, (CrCl: Creatinine Clearance)  
**Exclusion criteria:**  
Pregnancy or lactation Infection for human immunodeficiency viruses (HIV) , hepatitis B virus (HBV) or hepatitis C virus (HCV) Patients with other serious systemic diseases or malignancies Inability to provide informed consent or compliance with test conditions

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **15**  
Actual sample size reached: **14**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Motamed Cancer Institute Academic Center for Education Culture and Rese

##### Street address

No 146- South Ghandi-Vanaq Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1517964311

#### Approval date

2020-05-06, 1399/02/17

#### Ethics committee reference number

IR.ACECR.IBCRC.REC.1399.005

## Health conditions studied

### 1

#### Description of health condition studied

SARS-COV-2 related pneumonia

#### ICD-10 code

B34.2

#### ICD-10 code description

Coronavirus infection, unspecified

## Primary outcomes

### 1

#### Description

Possible hypersensitivity, Allergy symptoms

#### Timepoint

Daily to release date

#### Method of measurement

Physical examinations, Vital signs and respiratory symptoms monitoring via ICU equipment's and blood tests

### 2

#### Description

Improve severe respiratory symptoms

#### Timepoint

Daily to release date

#### Method of measurement

Blood oxygen levels, respiration volume, physical examinations

### 3

#### Description

Anaphylactic shock

#### Timepoint

Daily to release date

## Method of measurement

Physical examinations, Vital signs and respiratory symptoms monitoring via ICU equipment's and blood tests

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with resistant pneumonia caused by COVID-19 infection with acute symptoms of pneumonia who have not responded to routine treatments. This group will receive 2 to 10\*10<sup>6</sup> cells/Kg Good manufacturing practices (GMP)-grade Natural Killer cell infusion over 10 minutes. The common treatments of patients will not be stopped.

#### Category

Treatment - Other

### 2

#### Description

Control group: Patients with resistant pneumonia caused by COVID-19 infection with acute symptoms of pneumonia who did not respond to routine treatments. This group would be normalized in case of age and gender and given routine treatments.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Dr Atefeh Abedini

##### Street address

No146-South Ghandi-Vanaq Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1517964311

##### Phone

+98 21 8879 6003

##### Email

dr.abedini110@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Motamed Cancer Institute

#### Full name of responsible person

Dr Keivan Majidzadeh Ardebili

#### Street address

No 146-South Ghandi -Vanaq Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1517964311

#### Phone

+98 21 8879 6003

#### Email

K1majidzadeh@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Motamed Cancer Institute

#### Proportion provided by this source

10

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Other

### 2

#### Sponsor

##### Name of organization / entity

Modiriat Atiye Bahman Company

##### Full name of responsible person

Sina Hasanalizadeh

##### Street address

No-1,Ghasemi-tabatabaei

##### City

Tehran

##### Province

Tehran

##### Postal code

1459973114

##### Phone

+98 21 8879 6003

##### Email

rsf1351@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Modiriat Atiye Bahman Company

#### Proportion provided by this source

90

**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**

Other

Tehran

**Province**

Tehran

**Postal code**

1517964311

**Phone**

+98 21 8879 6003

**Email**

rsf1351@gmail.com

**Person responsible for general inquiries****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Dr Ramin Sarrami Forooshani

**Position**

Associated Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Virology

**Street address**

No146-Vanaq- South Ghandi- Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1517964311

**Phone**

+98 21 8879 6003

**Email**

rsf1351@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Dr Ramin Sarrami Forooshani

**Position**

Associated professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Virology

**Street address**

No 146-South Ghandi-Vanaq Aquare

**City****Person responsible for updating data****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Mahdieh Shokrollahi Barough

**Position**

Professor Assistant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

**Street address**

No 146-South Ghandi-Vanaq Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1517964311

**Phone**

+98 21 8879 6003

**Email**

m-shokrollahi@farabi.tums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable