Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 (2x10^6 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 (2-10x10^6/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*10^6 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Motamed Cancer Institute
Full name of responsible person
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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
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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

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
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Virology
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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