Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the safety and efficacy of allogeneic activated Natural killer cells in metastatic Colon Adenocarcinoma

Protocol summary

Study aim
Evaluation of the safety and efficacy of activated allogeneic natural killer cells in patients with metastatic colon adenocarcinoma

Design
This study is a single-arm phase 1 and 2 clinical trial, on 10 patients.

Settings and conduct
Setting: Taleghani hospital, Shahid Beheshti University of Medical Sciences. Infusion of six rounds of NK cells in two three-stage cycles. The interval between each injection is two weeks. The time interval between two cycles is three weeks. Final evaluation one month after the last injection.

Participants/Inclusion and exclusion criteria
Patients with metastatic colon adenocarcinoma who have received at least two lines of standard treatment regimen and presented with disease progression. After fully explaining the objectives of the study, the patients enter the study with informed consent and fill in the consent form. Age between 18 and 75 years, both male and female. The expected survival period of the participants is at least 6 months. Patients with metastatic colon adenocarcinoma who have failed at least two standard lines of treatment and no other viable and effective treatment is available. It is possible to evaluate the metastatic lesion in the participants by radiological approaches. (CT and MRI) The physical condition score of ECOG participants is 0-2. Participants should have proper liver, kidney, and bone marrow function. Participants must be willing and able to comply with planned treatment regimens, laboratory tests, follow-up visits, and other study requirements. Participants should be HIV-negative and not have active hepatitis B and C.

Intervention groups
activated allogeneic natural killer cells

Main outcome variables
The amount of tumor markers in the blood (CEA, CA19.9)
Radiological evaluations of metastatic lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230704058675N1**
Registration date: **2023-10-23, 1402/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-23, 1402/08/01**
Update count: **0**

Registration date
2023-10-23, 1402/08/01

Registrant information

Name
Sara zehtabcheh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6619 4372

Email address
s.zehtab@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-22, 1402/07/30

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the safety and efficacy of allogeneic activated Natural killer cells in metastatic Colon Adenocarcinoma

Public title

Evaluation of the safety and efficacy of allogeneic activated Natural killer cells in metastatic Colon Adenocarcinoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The expected survival period of the participants is at least 6 months Patients with metastatic colon adenocarcinoma who have failed at least two standard lines of treatment and no other viable and effective treatment is available. It should be possible to evaluate the metastatic lesion in the participants by radiological approaches. (CT and MRI) The physical condition score of ECOG participants is 0-2. Participants should have proper liver, kidney, and bone marrow function. Laboratory screening must meet the following criteria for all laboratory tests. WBC ≥ 1.5 x 109/L. PLT platelet count ≥60×109/L. Hemoglobin Hb content of 8.0 g/dL or higher. Lymphocyte LYM≥0.4×109/L. Serum creatinine ≤1.5 × ULN, if serum creatinine > 1.5 × ULN, creatinine clearance rate > 50 mL/min (calculated according to the Cockcroft-Gault formula). Total serum bilirubin ≤1.5×ULN, ALT≤2×ULN, AST≤2×ULN (patients with liver metastasis or liver cancer) ALT≤5 x ULN, AST≤5 x ULN). Amylase and lipase ≤ 1.5 × ULN. Urine protein < 2+ Participants must be willing and able to comply with planned treatment regimens, laboratory tests, follow-up visits, and other study requirements. Participants should be HIV negative and don't have active hepatitis B and C

Exclusion criteria:

Patients with (MSI-H) phenotype will not be included in the study. (Patients with MSS molecular status will be included in the study). Patients with metastasis in CNS or BM Prior immunotherapy with NK or CAR-NK received anti-PD-1/PD-L1 monoclonal antibody therapy within 4 weeks prior to treatment Patients who have previously received other gene therapies Patients who participated in other clinical studies in the last 1 month Participants who have not received a maximum of 2 series of intermittent TB therapy out of 6 series of cell injections. known history of human immunodeficiency virus (HIV) infection; acute or chronic active hepatitis B (HBsAg positive); Acute or chronic active hepatitis C (HCV antibody positive). Syphilis antibody positive; DNA quantity of Epstein-Barr virus 500 copies; Cytomegalovirus (CMV) infection (IgM positive). Severe infection that is active or clinically poorly controlled. Existing heart disease requiring treatment or hypertension not well controlled by the investigator (systolic blood pressure ≥140 mmHg and/or diastolic blood pressure >90 mmHg after treatment). The presence of any clinical symptoms or heart diseases (ischemic heart disease, heart failure and arrhythmia) Patients with chronic lung, heart and liver diseases. Patients with active autoimmune disease; Rheumatoid arthritis, inflammatory bowel disease, celiac disease, systemic lupus erythematosus, scleroderma and multiple sclerosis. Patients taking immunosuppressive drugs, including tacrolimus, mycophenolate mofetil, sirolimus, and cyclosporine A. Patients with psychiatric diseases from whom it is not possible to obtain informed consent. Abnormal coagulation function (INR > 1.5), bleeding tendency, or receiving thrombolytic or conventional anticoagulant therapy (eg, warfarin or heparin) in patients requiring long-term antiplatelet therapy (aspirin > 300 mg/day; clopidogrel, dose > 75 mg per day). People requiring systemic treatment with corticosteroids or other immunosuppressive agents during the course of treatment. Known past or present hepatic encephalopathy requiring treatment. Patients who currently have or have a history of central nervous system disorders such as epilepsy, seizures, cerebral ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease associated with central nervous system involvement. Patients with previous or simultaneous malignancy Participants who drop out of the study for various reasons and cannot participate in the study again

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

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

Vice President of Research and Technology Shahid Beheshti University of Medical Sciences (Research E

Street address

Shahid Beheshti Medical university, Yaman St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code
1985717443
Approval date
2023-09-30, 1402/07/08
Ethics committee reference number
IR.SBMU.RETECH.REC.1402.361

Health conditions studied

1

Description of health condition studied
Patients with metastatic colon adenocarcinoma
ICD-10 code
C18.9
ICD-10 code description
Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description
Evaluation of response to treatment
Timepoint
before the start of the study and one month after the last intervention
Method of measurement
The amount of tumor markers in the blood (CEA, CA19.9)

2

Description
Evaluation of response to treatment
Timepoint
before the start of the study and one month after the last intervention
Method of measurement
Radiological evaluations of metastatic lesions

Secondary outcomes

empty

Intervention groups

1

Description
Patients with metastatic colon adenocarcinoma who have received at least two lines of standard treatment regimen and presented with disease progression.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Sina Salari
Street address
Arabi St, Yaman St, Shahid Chamran highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
salari.sina52@gmail.com

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
Tehran
Province
Tehran
Postal code
14965161
Phone
+98 21 4478 7327
Email
shojaeisahar@gmail.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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sara Zehtabcheh
Position
Ph.D. Candidate
Latest degree
Ph.D.
Other areas of specialty/work
Hematology
Street address
Darband St, Qods Sq, Tajrish Sq, Tehran
City
Tehran
Province
Tehran
Postal code
1971653313
Phone
+98 21 2271 8528
Email
s.zehtab9393@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sina Salari
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Arabi St, Yaman St, Shahid Chamran highway, Tehran
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
salari.sina52@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sara Zehtabcheh
Position
Ph.D. Candidate
Latest degree
Ph.D.
Other areas of specialty/work
Hematology
Street address
Darband St, QodsSqu, Tajrish Squ, Tehran
City
Tehran
Province
Tehran
Postal code
1971653313
Phone
+98 21 2271 8528
Email
s.zehtab9393@gmail.com

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