

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Combinational Cell Therapy using Natural Killer Cells and Erbitux in Patients with Advanced Gastric Adenocarcinoma

Protocol summary

Study aim

Combinational Cell Therapy using NK cells and Erbitux in Patients with Advanced Gastric Adenocarcinoma

Design

A pilot single arm clinical trial of 6 patients

Settings and conduct

1- Patient selection. 2- Isolation of mononuclear cells isolated using ficoll and density gradient centrifugation and then using an NK cells isolation kit, NK cells will be separated 3- Pretreatment of NK cells with Anti-NKG2A 4- Injection protocol including conditioning regime, erbitux injection, and intravenously injection of 7×10^8 cells

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age between 20 and 60 years - Histologically confirmed adenocarcinoma of the stomach - Patients who have relapsed at least once after gastrectomy and did not respond to chemotherapy. - Patients receiving the same chemotherapy regimen. - Patients with the same tumor size. - Diffuse form of histopathology. - Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 - Life expectancy of at least 3 months - Absence of heart problems - Proper functioning of vital organs Exclusion criteria: - Positive test for HIV, HTLV-1, syphilis, hepatitis B and C infections - Severe active infection - Serious complications such as diabetes mellitus, unstable angina, or myocardial infarction within 3 months - Pregnancy or lactation period - History of autoimmune diseases and hypersensitivity - History of receiving any type of cell therapy in the last 6 months

Intervention groups

Intravenous injection of Erbitux and the number of 7×10^5 NK cells in 3 periods with an interval of 5 days to 3 patients with GAC Control group: Erbitux with a dose of 400 mg/m² one day before the start of cell therapy and repeat for every 2 weeks up to 3 doses of injection

Main outcome variables

Follow-up of patients after each injection and 28 days after the last injection based on clinical response and

safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N36**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

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
Combinational Cell Therapy using Natural Killer Cells and Erbitux in Patients with Advanced Gastric Adenocarcinoma

Public title
Combinational Cell Therapy using Natural Killer Cells and Erbitux in Patients with Advanced Gastric Adenocarcinoma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years- Histologically confirmed adenocarcinoma of the stomach- Patients who have relapsed at least once after gastrectomy and did not respond to chemotherapy.- Patients receiving the same chemotherapy regimen.- Patients with the same tumor size.- Diffuse form of histopathology.- Eastern Cooperative Oncology Group (ECOG) performance status<2- Life expectancy of at least 3 months- Absence of heart problems- Proper functioning of vital organs:leukocyte count $\geq 3000/\text{mm}^3$ neutrophil count $\geq 1500/\text{mm}^3$ platelet count $\geq 100,000/\text{mm}^3$ hemoglobin ≥ 9.0 g/dLserum aspartate aminotransferase (AST) ≤ 100 IU/Lalanine aminotransferase (ALT) ≤ 100 IU/Lserum total bilirubin ≤ 2 mg/dLserum creatinine ≤ 1.5 mg/dLblood urea ≤ 25 mg/dL
Exclusion criteria:
- Positive test for HIV, HTLV-1, syphilis, hepatitis B and C infections- Severe active infection- Serious complications such as diabetes mellitus, unstable angina, or myocardial infarction within 3 months- Pregnancy or lactation period- History of autoimmune diseases and hypersensitivity- History of receiving any type of cell therapy in the last 6 months

Age
From **20 years** old to **60 months** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **3**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical

Street address

3rd Floor, No 10, Endocrinology and Metabolism Research Institute, Jalal-AI-Ahmad St., Chamran Hwy., Tehran-Iran

City

Tehran

Province

Tehran

Postal code

1411713119

Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.080

Health conditions studied

1

Description of health condition studied

Gastric Adenocarcinoma

ICD-10 code

C16. 9

ICD-10 code description

C16. 9 Malignant neoplasm: Stomach, unspecified

Primary outcomes

1

Description

Checking the safety and toxicity of the injected cells

Timepoint

28 days

Method of measurement

Any side effects related to cell injection will be checked and recorded during the injection and up to 28 days after the injection.If a complication is seen during or after the infusion, the following actions will be taken based on the CTCAE guideline:In grade 1, only the infusion is stopped.In grades 2 and 3, the infusion is stopped along with anti-allergic treatments, including corticosteroids and antihistamines.In grade 4, in addition to the above, resuscitation measures and care in the ICU department are also recommended.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous injection of Erbitux according to the standard protocol and the number of 7×10^5 NK cells in 3 periods with an interval of 5 days to 3 patients with advanced cancer GAC

Category

Treatment - Other

2

Description

Control group: Erbitux is injected intravenously with a dose of 400 mg/m² one day before the start of the first cycle of cell injection. Then every 2 weeks up to 3 doses of injection will be repeated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr Maryam Barkhordar

Street address

Kargar Shomali Ave, Shariati Hospital, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Proportion provided by this source

100

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Javad Verdi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Latest degree

Ph.D.

Other areas of specialty/work

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

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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

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

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