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 7x10^8 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 7x10^5 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
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Name of organization / entity
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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 ≥3000/mm3neutrophil count ≥1500/mm3platelet count ≥100,000/mm3hemoglobin ≥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-Al-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 7x10^5 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/m^2one 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
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Kargar Shomali Ave, Shariati Hospital, Tehran
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Sponsors / Funding sources

1

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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
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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