Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Clinical evaluation of immunogenic adjuvant therapy with dendritic cells loaded with autologous tumor mRNA in patients with gastric cancer

Protocol summary

Study aim
Clinical evaluation of immunogenic adjuvant therapy with dendritic cells loaded with autologous tumor mRNA

Design
Patients are divided into three groups based on cell dose levels. Patients can be vaccinated with low dose, medium dose and high dose in four times.

Settings and conduct
Mashhad university of medical science Production of immature dendritic cells from the patient's peripheral blood monocytes, adjacency of these cells with the patient's tumor antigens, induction of puberty, injection of adult dendritic cells into the patient.

Participants/Inclusion and exclusion criteria
If the patient has systemic diseases such as severe respiratory disease, immunodeficiency diseases that may interfere with the outcome of treatment or other problems for the patient; The use of corticosteroids to treat the patient in the apheresis stage is permitted but is prohibited in the immunotherapy stage and should be discontinued at least 2 weeks before the start of immunotherapy. Except for inhaled or topical dermal steroids; Patients with hepatitis B, hepatitis C and HIV and any type of active infection in general; Patients with a developing or refractory tumor will not be excluded from standard chemotherapy treatments;Patients who need chemotherapy or radiotherapy for any reason during immunotherapy; Liver enzymes more than 5 times normal; Total serum bilirubin equal to or greater than 5 mg / dL; Serum creatinine more than 2 mg / dL); White blood cell count less than 2500 per cubic millimeter of blood; Platelet count less than 100,000 per cubic millimeter of blood; Pregnancy and lactation; Another malignancy in the last 5 years; Injecting drug addiction; Failure to sign the agreement.

Intervention groups
Dendritic cells loaded with tumor antigen

Main outcome variables
Side effects within 72 hours

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170208032451N1**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **prospective**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date
2020-09-14, 1399/06/24

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3711 2343
Email address
abbaszadeganmr@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical evaluation of immunogenic adjuvant therapy with

dendritic cells loaded with autologous tumor mRNA in patients with gastric cancer

Public title
Gastric cancer immunotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with gastric adenocarcinoma whose histologically advanced malignancy (spread of cancer cells to lymph nodes and tumor metastasis) has been confirmed and they have filled out the informed consent form The patient must be over 18 years old at the time of diagnosis. Natural laboratory parameters, including these tests: Protein C& S, D-Dimer, VWF, CPK,LDH, TI, ALP, Lipase, Amylase, GGT, OB,CBC diff, Hgb electrophoresis, Serum Iron, Transferrin saturation, TIBC, CH50 (total complement), ESR, CRP, ACE, ANA, Anti CCP, RF, Auto antibodies, UA, Uric acid, Cr, Urea, SGPT, SGOT, Bilirubin, Albumin, Lipid profile, ACTH, Cortisol, FBS, HbA1c, OGT , ACTH, Cortisol, FBS, HbA1c, OGTT, Insulin, PTH, GH, Calcitonin, TFT, Testosterone, LH, FSH, Estrogen, Progestrone, PRL. To start immunotherapy, at least 4 weeks must have passed since the last course of chemotherapy or radiotherapy, and all the side effects of chemotherapy must be eliminated. Functional condition according to Karnowski criteria should be more than 60% Expected survival rate more than 6 months
Exclusion criteria:
brain metastasis autoimmune diseases Abnormal function of heart, liver, kidney, brain and other important organs
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **5**
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
mashhad university of medical sciences
Street address
East door of Ferdowsi University, Public Relations Department of the University
City
mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2020-01-28, 1398/11/08
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.100

Health conditions studied

1

Description of health condition studied
gastric cancer
ICD-10 code
C16
ICD-10 code description
Malignant neoplasm of stomach

Primary outcomes

1

Description
side effect
Timepoint
7 days
Method of measurement
clinical measurement

Secondary outcomes

1

Description
clinical and immune response
Timepoint
one year
Method of measurement
Flow cytometry - ELISA - Overall survival rate - Tumor-free survival rate

Intervention groups

1

Description
Chimer Construction Design: using immunogenetic epitopes of MAGEA4, LAGE1, and NY-ESO1 antigens, a chimeric molecule is prepared which, due to the pivotal role of dendritic cells in inducing an immune response, is

sent into these cells in the form of mRNA to stimulate the immune system. Provide gastric cancer patients. Due to the overexpression of selective markers (MAGE-A4, LAGE1, and NY-ESO1) in gastric tumor cells compared to normal cells, the structural basis of the construct molecule was based on specific sequences of the same genes. Our goal is to identify these proteins to lymphocyte cells as tumor markers. Since it is difficult to transfer the complete gene or mRNA of all three markers to the antigen-supplying cells, parts of each protein were selected and synthesized together into one molecule.Construction of contraceptive mRNA by Mmessage Mmachin kit:Plasmid PGEM-4Z / GFP / A64, which has a polymythine sequence at the end of the transcription region, is used as the target vector for the synthesized construct. Chimeric Antigene mRNA amplification is performed using an in vitro transcription reaction.Leukophoresis and isolation of monocytes from peripheral blood:Isolation of diseased monocytes and lymphocytes from peripheral blood mononuclear cells (PBMC) is performed by leukophoresis. After isolation of monocytes and lymphocytes by specific leukophoresis kits, the cells were transferred to the laboratory to be converted to DC cells in vitro. In order to isolate T lymphocytes, which are required in the next stages of the test, using the conventional method of attaching monocyte cells to the bottom of the culture flask, the unattached cells are the same T lymphocytes that are used for the next steps of the test. Placed.Production of dendritic immature cells (DC immature): According to the standard instructions of blood monocytes, under laboratory culture and with the addition of cytokines GM-CSF, IL-4 at specific concentrations within 5 to 7 days, monocytes become immature dendritic cells. At the end of this stage, the produced cells of dendritic cell or DC immature are evaluated by flow cytometry.Transfer of Chimeric Antigene mRNA to immature DC cells (DC loading):At this stage, immature DC cells are transferred to the DC cell with Chimeric Antigene mRNA 25 µg / mL by nanoparticle.DC maturation stage by cytokine mixture:At this stage, the loaded DCs are placed in the vicinity of the maturation stimuli to mature. In RPMI-1640 culture medium, cytokine cocktail containing a mixture of cytokines IL-1, IL-6, PGE2, TNF-□ is performed in 2-3 days of DC cell maturation stages.Phenotypic study of produced DC cells:This operation is performed by flow cytometry device and monoclonal antibodies by examining CCR7, CD83, CD14, CD86, CD80 and HLA-DR markers.648/5000Vaccination schedule:Patients are divided into two groups based on cell dose levels. The first measurable patient was vaccinated with a low dose (injection / cell dose 107.1), the second measurable patient with a moderate dose (injection / cell dose 107.3), and the third measurable patient with a high dose (injection / cell dose 108.1). To be. Four consecutive vaccinations with dendritic cells loaded with chimeric antigens are performed intravenously once a week (21-day period). The fourth and fifth patients inject dendritic cells loaded with dendritic antigens intravenously (injection / cell dose 106 × 1) intradermally into the forearm or thigh 4 times with an interval of two weeks between each vaccine. To turn.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
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2

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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mohammad Reza Rbbaszadegan

Position
Professor

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available