Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the safety and efficacy of cell therapy with Tumor-Infiltrating Lymphocytes (TILs) in the Triple Negative Breast Cancer

Protocol summary

Study aim
Investigating the safety and efficacy of cell therapy with Tumor-Infiltrating Lymphocytes (TILs) in the Triple Negative Breast Cancer

Design
A single-arm non-randomized, phase 1-2 clinical trial on 10 patients

Settings and conduct
This single-group clinical trial will be performed at the Hematology-Oncology-Stem Cell Transplantation Research Center (HORCSCT) of Tehran University on ten adult patients with Triple Negative Breast Cancer who have relapsed following standard initial treatment. After a conditioning lymphodepletion regimen, a total dose of one billion (10 thousand million) cells, prepared in the laboratory environment, will be injected into patients.

Participants/Inclusion and exclusion criteria
The patients should have triple-negative breast cancer and have received at least one line of systemic cancer treatment. Patients should have at least one resectable lesion with a minimum diameter of 1.5 cm after removal to produce the TILs research. Patients with immune deficiencies, patients who have been vaccinated over the past six months, AIDS patients, patients with systemic steroid treatment, and patients with severe active infection do not enter the study.

Intervention groups
A fresh biopsy sample is prepared from the patient's tumor tissue and cultured for 14 days in a culture medium under GMP conditions for cell processing. Before cell therapy, patients receive an immunosuppressive regimen, including fludarabine and cyclophosphamide. And then, the prepared TILs cells with a total dose of one billion (10 thousand million) cells are injected intravenously.

Main outcome variables
Number of Patients with Grades 3-5 of TILs infusion-related Adverse Events; Objective Response Rate using the Response Evaluation Criteria in Solid Tumors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140818018842N34**
Registration date: **2023-04-25, 1402/02/05**
Registration timing: **prospective**

Last update: **2023-04-25, 1402/02/05**
Update count: **0**

Registration date
2023-04-25, 1402/02/05

Registrant information

Name
Leyla Sharifi Aliabadi

Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-10, 1402/02/20

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the safety and efficacy of cell therapy with Tumor-Infiltrating Lymphocytes (TILs) in the Triple Negative Breast Cancer

Public title
Tumor-infiltrating Lymphocytes therapy in Breast Cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ability to understand the requirements of the study. Specifically, the patient has to provide written informed consent All patients must have triple-negative breast cancer as defined by the 2018 ASCO guidelines. Patients must have at least one resectable lesion of a minimum of 1.5 cm in diameter post-resection for TILs investigational production. Patients must be ≥ 18 years of age at the time of consent. The patients of childbearing potential must be willing to practice an approved method of birth control during treatment and 12 months after receiving all protocol-related therapy. Patients must have adequate bone marrow function Patients must have adequate organ function: Patients must be seronegative for the human immunodeficiency virus (HIV1 and HIV2). Patients must have recovered from all prior anticancer treatment-related adverse events. Patients must have provided written authorization to use and disclose protected health information. Patients must be able and willing to comply with the study visit schedule and protocol requirements, including long-term follow-up (LTFU).

Exclusion criteria:
Participation in other clinical trials Patients who have received a vaccine over the past 6 months. Patients with immune deficiencies Patients undergoing systemic steroidal treated Patients who have a history of any cell therapy in the last six months Patients with a severe active infection

Age
From **18 years** old to **65 years** old

Gender
Female

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
Ethic committee of Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran Univer

Street address
Kargar shomali Ave., Shariati hospital

City
tehran

Province
Tehran

Postal code
1411713131

Approval date
2023-01-25, 1401/11/05

Ethics committee reference number
IR.TUMS.HORCSCT.REC.1401.035

Health conditions studied

1

Description of health condition studied
Triple negative breast cancer

ICD-10 code
ICD-50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Number of Patients With Grades 3-5 of TILs infusion-related Adverse Events (Version 4.03)

Timepoint
Daily during the seven days after the injection

Method of measurement
Physical exam, history and lab tests

2

Description
Objective Response Rate using the Response Evaluation Criteria in Solid Tumors (RECIST)

Timepoint
Before intervention and 1, 3 months after the intervention

Method of measurement
Assessment of tumor size by computed tomography (CT) or magnetic resonance imaging (MRI)

Secondary outcomes

1

Description
Duration of response (DOR)
Timepoint
Every 3 months till one year
Method of measurement
Assessment of tumor size by computed tomography (CT) or magnetic resonance imaging (MRI)

Intervention groups

1

Description
Intervention group: In this study, 10 patients with triple-negative breast cancer who have relapsed following standard initial treatment are included. A fresh biopsy sample is prepared from the patient's tumor tissue and transferred to RPMI 1640 medium with antibiotics for cell processing. The sample is crushed and made into single cells by an enzymatic method (collagenase type 4 enzyme). TIL cells are then cultivated for 14 days in a culture medium containing the anti-CD3 antibody and human IL-2 and irradiated feeder cells under GMP conditions. Patients receive a conditioning lymphodepletion regimen before the TILs. It includes the infusion of 25 mg/mm Fludarabine from seven to four days before the TILs (days -7 to - 4), followed by cyclophosphamide 25mg/kg on days -3 and -2. And then, a total dose of 10 billion (10 thousand million) cells, prepared in the laboratory environment, will be injected on day zero.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci
Full name of responsible person
Mohamad Ahmadvand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mohamad Ahmadvand
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Hematology
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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

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