

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Personalized Immunology of Patients with Advanced Breast Cancer Using induced Pluripotent Stem Cell-Derived Natural Killer cells

Protocol summary

Study aim

The main goal of this phase I clinical trial is to evaluate the safety and efficacy of personalized induced pluripotent stem cell-derived natural killer cell therapy on patients with advanced breast cancer.

Design

The present study is a single-group non-randomized phase I clinical trial with non-blinded post- and pre-intervention outcome assessment.

Settings and conduct

Following obtaining informed consent, a simple skin biopsy from the candidate's mastoid area will be taken for iPSCs manipulation and then NK cells generation. Finally, patients receive a determined dosage of the generated NK cells through three infusions. All of the evaluations will be conducted at the Cancer Institute of Imam Khomeini Hospital, Tehran, Iran.

Participants/Inclusion and exclusion criteria

The ideal candidates for this study are those with: women between 20 to 70 years of age with the diagnosis of advanced breast cancer by any combination of ER, PR, and HER-2, who are a metastasis lesions and progressed on chemotherapy and/or radiotherapy.

Intervention groups

In this single-group study, 32 patients will be non-randomly recruited. Besides their routine medications, the candidates receive a determined dosage of the generated NK cells (8-10 billion cell/m²) through three infusions courses.

Main outcome variables

Determination of probable toxicity, response to treatment, progression-free survival (PFS), and immune system function following the intervention.

General information

Reason for update

Acronym

iTC Study

IRCT registration information

IRCT registration number: **IRCT20200429047241N1**

Registration date: **2020-08-10, 1399/05/20**

Registration timing: **prospective**

Last update: **2020-08-10, 1399/05/20**

Update count: **0**

Registration date

2020-08-10, 1399/05/20

Registrant information

Name

Habibollah Mahmoodzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2509

Email address

hmahmoodzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2025-02-18, 1403/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Personalized Immunology of Patients with Advanced Breast Cancer Using induced Pluripotent Stem Cell-Derived Natural Killer cells

Public title

A Clinical Trial to Evaluate the Effects of Autologous induced Pluripotent Stem Cell-Derived Natural Killer Cells in Personalized Treatment of Patients with Advanced Metastatic Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with the diagnosis of ABC by any combination of ER, PR, and HER-2, who are progressed on chemotherapy and/or radiotherapy regimens for their metastatic disease. Single metastasis patients with a measurable metastasis in the lymph node, lung, liver, and bone. Women must be between 20 and 70 years of age.

Exclusion criteria:

Patients with active and uncontrolled infections. Abnormal kidney, lung and liver function, measured by serum creatinine (serum creatinine > 2 mg / dl), saturated oxygen O₂ ≤ 96%) (Sat and liver enzymes (ALT / AST > 2.5 × N). Patients with the other types of cancers unrelated to the primary breast tumors

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **32**

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- Chancellor in Research Affairs-Tehran University of Medical Science

Street address

Cancer Institute, Imam Khomeini Hospital Complex, Doctor Qarib, Keshavarz Boulevard, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-06-08, 1398/03/18

Ethics committee reference number

IR.TUMS.VCR.REC.1398.232

Health conditions studied**1****Description of health condition studied**

Advanced Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Probable toxicity resulting from Intervention

Timepoint

Pre- and post-intervention

Method of measurement

Physical examination, biochemical and serological tests, and electrocardiography

2**Description**

Response to treatment

Timepoint

Pre- and post-intervention

Method of measurement

CT scan, histopathologic observations, and plasma level of tumor markers

3**Description**

progression-free survival

Timepoint

post-intervention

Method of measurement

Follow-up

4**Description**

Immune system function

Timepoint

Pre- and post-intervention

Method of measurement

Flow cytometry and ELIZA cytokine assay

Secondary outcomes

empty

Intervention groups

1

Description

Candidates besides their standard treatments receive a determined dosage of the generated NK cells (8-10 billion cell/m²) through three intravenous infusions courses.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Instituted of Iran, Imam Khomeini complex medical center, Tehran, Iran.

Full name of responsible person

Dr. Habibollah Mahmoodzadeh

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Cancer Instituted, Imam Khomeini complex medical center, Keshavarz Boulevard, Doctor Qharib Street, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Center for Personalized Medicine (ICPM)

Full name of responsible person

Dr. Karim Nayernia

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Luise-Rainer

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Düsseldorf

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40235

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Email

nayernia@p7medicine.com

Web page address

<http://www.icpm.center/>

Grant name

Grant code / Reference number

ICPM-2019-001

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

International Center for Personalized Medicine (ICPM)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

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

Hamid Khodayari

Position

Researcher

Latest degree

Bachelor

Other areas of specialty/work

Cancer Research

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Surgical Oncology

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

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Full name of responsible person

Hamid Khodayari

Position

Researcher

Latest degree

Bachelor

Other areas of specialty/work

Cancer Research

Street addressCancer Institute of Iran, Imam Khomeini Hospital
Complex, Tohid Squire, Tehran, Iran**City**

Tehran

Province**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