

# 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/m<sup>2</sup>) 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 O<sub>2</sub> ≤ 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/m<sup>2</sup>) 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

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 6658 1587

#### Email

hmahmoodzadeh@tums.ac.ir

#### Web page address

<http://www.ikhc.tums.ac.ir>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

International Center for Personalized Medicine (ICPM)

#### Full name of responsible person

Dr. Karim Nayernia

#### Street address

Luise-Rainer

#### City

Düsseldorf

#### Postal code

40235

#### Phone

+49 211 436912110

#### 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

#### Street address

Cancer Institute of Iran, Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

#### City

Tehran

#### Province

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#### Postal code

۱۴۱۹۷۳۳۱۴۱

#### Phone

+98 21 6658 1587

#### Email

h.khodayari@hotmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Habibolah Mahmoodzadeh

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Surgical Oncology

#### Street address

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

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**Other areas of specialty/work**

Cancer Research

**Street address**Cancer 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