

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### Investigation of the safety of autologous immune cells injection enriched with NK (Natural killer) cells to the patients with refractory breast cancer

#### Protocol summary

##### Study aim

Investigation of the safety of autologous immune cells injection enriched with NK (Natural killer) cells to the patients with refractory breast cancer

##### Design

In the present study, one group including three refractory breast cancer patients with inclusion criteria enrolled.

##### Settings and conduct

In this study, after peripheral blood mononuclear cells isolation, the cells will be co-cultured, activate and proliferate with the specific antibodies and the culture medium for two weeks in the clean room, then the cells will be injected to the patients. This process will be performed every 2 weeks during 3 months (6 injections)

##### Participants/Inclusion and exclusion criteria

Female patients with refractory breast cancer, Infiltrative Ductal Carcinoma (IDC) type, without any infection, autoimmune disease, and pregnancy will participate in the study.

##### Intervention groups

One group of patients including 3 patients with refractory breast cancer will participate in this study. Autologous immune cells enriched with Natural killer cells will be injected to the patients every two weeks during three months (six injections).

##### Main outcome variables

Investigation of the safety of the autologous immune cells enriched with Natural killer cells injection to the patients with refractory breast cancer is the main outcome variable of the present study.

#### General information

##### Reason for update

##### Acronym

ICR-NKCT-17

##### IRCT registration information

IRCT registration number: **IRCT20160419027479N2**

Registration date: **2018-02-14, 1396/11/25**

Registration timing: **prospective**

Last update: **2018-03-01, 1396/12/10**

Update count: **1**

##### Registration date

2018-02-14, 1396/11/25

##### Registrant information

###### Name

Dr. Nasrollah Erfani

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3230 3687

###### Email address

erfanin@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

VC for research and technology and Institute for Stem Cells and Regenerative Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of the safety of autologous immune cells injection enriched with NK (Natural killer) cells to the

patients with refractory breast cancer

## Public title

Investigation of treatment of patients with refractory breast cancer using autologous immune cells enriched with NK cells

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with breast cancer, Infiltrative Ductal Carcinoma (IDC) Patients with end stage breast cancer (Stage 4) Patients with refractory breast cancer based on National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines Triple negative (ER-,PR- and Her2-) breast cancer patients Patients with the minimum age of 18 years old and maximum 60 years old Performance status =0 or 1 Life expectancy for patients: more than 3 months

### Exclusion criteria:

Patients with autoimmune disease Patients with active infection Patients who spend the intensive radiotherapy Pregnant patients

## Age

From **18 years** old to **60 years** old

## Gender

Female

## Phase

1

## Groups that have been masked

No information

## Sample size

Target sample size: **3**

## Randomization (investigator's opinion)

Not randomized

## 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 in research, Shiraz University of Medical Sciences

##### Street address

Ethic committee, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran

##### City

Shiraz

## Province

Fars

## Postal code

71348-14336

## Approval date

2017-09-17, 1396/06/26

## Ethics committee reference number

IR.SUMS.REC.1396.104

## Health conditions studied

### 1

#### Description of health condition studied

Refractory breast cancer

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Determining how well NK enriched immune cells can be tolerated in patients. Safety and toxicity will be determined based on Common Terminology Criteria for Adverse Events (CTCAEs) guideline

#### Timepoint

The period between the first injection and 2 months after the last injection

#### Method of measurement

According to the CTCAEs [Common Terminology Criteria for Adverse Events]

## Secondary outcomes

### 1

#### Description

Immunological responses in the patients

#### Timepoint

The period between the first injection and 2 months after the last injection

#### Method of measurement

The flowcytometric analysis of different immune cells percentage including B, T (CD4+ and CD8+), NK subsets, CD4+ regulatory T cells in PBMCs isolated from the patients

## Intervention groups

### 1

#### Description

Autologous NK enriched immune cells injection into the patients every 2 weeks during 3 months

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Nasrollah erfani

**Street address**

Namazi hospital, Namazi square, shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Phone**

+98 71 3647 4332

**Email**

erfanin@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

VC for Research and Technology and Institute for stem cells and regenerative medicine, Shiraz Unive

**Full name of responsible person**

Dr. Nasrollah Erfani

**Street address**

Shiraz Institute for Cancer Research- Medical School- Zand Street-Shiraz

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**Province**

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7134845794

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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**

VC for Research and Technology and Institute for stem cells and regenerative medicine, Shiraz Unive

**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**

Shiraz University of Medical Sciences, Medical School, Shiraz Institute for Cancer Research

**Full name of responsible person**

Somayeh Rezaeifard

**Position**

Ph.D. Student

**Latest degree**

Master

**Other areas of specialty/work**

Immunology

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srezaeifard@sums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Nasrollah erfani

**Position**

PhD, Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work****Street address**

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<http://icr.sums.ac.ir/en/index.html>

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences, Medical School,  
Shiraz Institute for Cancer Research

#### Full name of responsible person

Somayeh Rezaeifard

#### Position

Ph.D. Student

#### Latest degree

Master

#### Other areas of specialty/work

#### Street address

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Zand Street-Shiraz

#### City

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#### Province

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#### Postal code

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+98 71 3230 3687

#### Fax

#### Email

srezaeifard@sums.ac.ir

#### Web page address

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

1) Clinical and pathological characteristics of the [patients, including tumor type, tumor grade, tumor stage, LN involvement and metastasis at the time of diagnosis 2) Clinical response to the treatment regimen, as well as the pathological and immunological findings before and after cell therapy

### When the data will become available and for how long

Six months following the publication of the results

### To whom data/document is available

Researchers, scientist and physicians

### Under which criteria data/document could be used

Using the data for research with the permission of the principal investigators

### From where data/document is obtainable

Dr. Nasrollah Erfani/ Mrs. Somayeh Rezaeifard Shiraz Institute for Cancer Research and Department of Immunology, School of Medicine Shiraz University of Medical Sciences Zand Av. Shiraz. Iran Tel: +98 (71) 32303687 email: erfani@sums.ac.ir/ srezaeifard@sums.ac.ir

### What processes are involved for a request to access data/document

1) Putting the application 2) Processing the application by the investigators 3) Providing the data in two weeks

### Comments

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