

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The expression level alterations of miRNAs 21, 155, 10b and Let-7a, and matrix metalloproteinases 1, 2, 9, 11 and 13 as biomarkers in response to surgery and chemotherapy in blood plasma of breast cancer patients

#### Protocol summary

##### Summary

One of the important problems in cancer treatment is its diagnosis in the early stages and evaluation of response to treatment. Therefore, using the appropriate diagnostic methods with high efficiency and proper biomarkers for diagnosis and treatment of cancer patients is necessary. The present study aims to evaluate the expression level alterations of miRNAs 21, 155, 10b and Let-7a, and also the blood plasma-derived Matrix metalloproteinases 1, 2, 9, 11 and 13 in breast cancer patients. Inclusion criteria are included 30 breast cancer patients who will refer to Cancer Institute of Imam Khomeini hospital from October 2016 until October 2017. After inclusion, 5 ml whole blood will be collected from all the patients in both stages of diagnosis and after the treatment (after surgery and chemotherapy). After centrifugation, all samples will be maintained at -80 °C until the assessment time. Then, RNA extraction from blood and tissue, cDNA synthesis and quantitative analyses for the expressions of miRNAs 10b, 155, 21 and Let-7a, and also Matrix metalloproteinases 1, 2, 9, 11 and 13 will be performed by gelatin quantitative zymography.

#### General information

##### Acronym

MicroRNAs; Metalloproteinases

##### IRCT registration information

IRCT registration number: **IRCT2016080818745N11**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-04, 1395/06/14

#### Registrant information

##### Name

Ali Mohammad Alizadeh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2501

##### Email address

aalizadeh@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2016-08-22, 1395/06/01

#### Expected recruitment end date

2018-03-21, 1397/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The expression level alterations of miRNAs 21, 155, 10b and Let-7a, and matrix metalloproteinases 1, 2, 9, 11 and 13 as biomarkers in response to surgery and chemotherapy in blood plasma of breast cancer patients

#### Public title

The expression level alterations of some biofactors as biomarkers in response to surgery and chemotherapy in blood plasma of breast cancer patients

#### Purpose

Diagnostic

## Inclusion/Exclusion criteria

Inclusion criteria: The patients with breast cancer; With written informed consent; 30-70 years old patients; The breast cancer patients in stages 2 and 3. Exclusion criteria: The patients with opioid addiction; The patients with the history of rheumatoid arthritis; The patients with the history of cancer.

## Age

From **30 years** old to **70 years** old

## Gender

Female

## Phase

0

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## 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

Ethics committee of Tehran University of Medical Sciences

##### Street address

Keshavarz Bulvar, Porsina Street

##### City

Tehran

##### Postal code

##### Approval date

2016-08-08, 1395/05/18

##### Ethics committee reference number

IR.TUMS.REC.1395.2800

## Health conditions studied

### 1

#### Description of health condition studied

Breast Cancer

#### ICD-10 code

C50.9

#### ICD-10 code description

Breast, unspecified

## Primary outcomes

### 1

#### Description

the alteration of plasma expression level of the miRNAs

#### Timepoint

before and after treatment

#### Method of measurement

Real-Time PCR

## Secondary outcomes

### 1

#### Description

the expressions of metalloproteinases level

#### Timepoint

before and after treatment

#### Method of measurement

Gelatin quantitative zymography

## Intervention groups

### 1

#### Description

Five ml whole blood of all patients will be collected in both stages of disease diagnosis and after the standard treatments.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Cancer Research Center, Cancer Institute of Iran

##### Full name of responsible person

Dr. Ali Mohammad Alizadeh

##### Street address

3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Uonesian

##### Street address

Keshavarz Bulvar, Porsina Street

##### City

Tehran

**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**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Cancer Research Center, Cancer Institute of Iran  
**Full name of responsible person**  
Dr. Ali Mohammad Alizadeh  
**Position**  
Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran  
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**Web page address**  
www.pccrg.org

## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
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www.pccrg.org

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*