# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Investigation of the effect of adding Desloratadine to neoadjuvant chemotherapy on the response to treatment and some of inflammatory factors in breast cancer patients

## Protocol summary

**Study aim**

Investigating the effect of adding Desloratadine to neoadjuvant chemotherapy in breast cancer patients

**Design**

The clinical trial has a control group, with parallel groups, single-blind, phase 3 of 104 patients with breast cancer, randomization will be done by stratified method and by simple random method.

**Settings and conduct**

This study is conducted in 5 Azar Hospital, Gorgan, in a single-blind way (patients do not know the type of their group), the control group is treated with neoadjuvant chemotherapy, and the intervention group is treated with neoadjuvant chemotherapy and Desloratadine 5mg, then at the end of 4 chemotherapy courses to evaluate the therapeutic response of the results with measurements RECIST standard and the level of serological tumor markers (CEA, CA15-3) are interpreted, blood samples of patients are measured to evaluate the serum level of cytokines, and gene expression changes in PBMC cells.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria include having newly diagnosed breast cancer and being candidates for neoadjuvant chemotherapy, no use of antihistamines, no asthma, and not having other cancers at the same time as breast cancer. Exclusion criteria include patients with immune disorders Patients who are not eligible for chemotherapy for any reason. Patients who have undergone breast surgery

**Intervention groups**

The intervention group includes 52 breast cancer patients treated with neoadjuvant chemotherapy along with Desloratadine drug and the control group includes 52 breast cancer patients treated with neoadjuvant chemotherapy.

**Main outcome variables**

Determining response to treatment based on changes in tumor size and lymph node involvement based on standard RECIST criteria.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230221057485N1**
Registration date: **2023-07-30, 1402/05/08**
Registration timing: **prospective**

Last update: **2023-07-30, 1402/05/08**
Update count: **0**

**Registration date**

2023-07-30, 1402/05/08

**Registrant information**

**Name**

Hossein Azimi

**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**

2023-08-01, 1402/05/10

**Expected recruitment end date**

2024-05-30, 1403/03/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the effect of adding Desloratadine to neoadjuvant chemotherapy on the response to treatment and some of inflammatory factors in breast cancer patients

**Public title**

The effect of adding Desloratadine to neoadjuvant chemotherapy in patients with breast cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Newly diagnosed breast cancer who are candidates for neoadjuvant chemotherapy (including patients with axillary lymphadenopathy, infraclavicular and supraclavicular lymphadenopathy/tumor size greater than 2 cm in triple-negative and Her2-enriched patients/skin involvement/inflammatory breast cancer and a large ratio of tumor to total breast). Not using antihistamines (anti-H1R and H2R receptors) No asthma Not having other cancers at the same time as breast cancer

**Exclusion criteria:**

Patients with immunological disorders Patients who are not eligible for chemotherapy Patients who have undergone breast surgery

**Age**

From **18 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done in a stratified manner. In this way, 34 people will be selected from among the qualified people in each of the classes. Then, by a simple random method (34 similar cards are prepared and the letter A is written on 17 cards and the letter B is written on the other 17 cards, and then the patients will be randomly assigned to groups.)

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants (patients) who do not know their group type, control or intervention.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

**Street address**

Golestan University of Medical Sciences, Shasat Kala road, Hirkan Blvd, Gorgan

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**Postal code**

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**Approval date**

2023-07-24, 1402/05/02

**Ethics committee reference number**

IR.GOUMS.REC.1402.121

## Health conditions studied

### 1

**Description of health condition studied**

Breast cancer

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

## Primary outcomes

### 1

**Description**

Response rate to treatment based on changes in tumor size and lymph node involvement

**Timepoint**

At the beginning of the study and 2 months after the start of the first course of chemotherapy

**Method of measurement**

RECIST criteria

### 2

**Description**

The serum level of tumor serological markers (CEA, CA15-3)

**Timepoint**

At the beginning of the study and 2 months after the start of the first course of chemotherapy

**Method of measurement**

ELISA method

## Secondary outcomes

### 1

**Description**
Serum level of Interleukin-6
**Timepoint**
At the beginning of the study and 2 months after the start of the first course of chemotherapy
**Method of measurement**
ELISA method

### 2

**Description**
Serum level of Tumor necrosis factor alpha
**Timepoint**
At the beginning of the study and 2 months after the start of the first course of chemotherapy
**Method of measurement**
ELISA method

### 3

**Description**
Serum level of Histamine
**Timepoint**
At the beginning of the study and 2 months after the start of the first course of chemotherapy
**Method of measurement**
ELISA method

### 4

**Description**
Expression level of Histamine receptor 1 (H1R), Toll-like receptor 4 (TLR4), and Nuclear factor kappa B (NF-kB)
**Timepoint**
At the beginning of the study and 2 months after the start of the first course of chemotherapy
**Method of measurement**
Real-time polymerase chain reaction (real-time PCR)

## Intervention groups

### 1

**Description**
Intervention group: 52 patients with breast cancer are randomly included in the intervention group. In addition to the neoadjuvant chemotherapy process, desloratadine 5mg (Neotadine® tablets manufactured by Abidi Company, Iran) is prescribed daily (oral) until the patient is re-examined (about 2 months). At the end of 4 chemotherapy courses (every two weeks), breast ultrasound is performed again to evaluate the treatment response. then blood samples (7-10 cc) are taken and the amount of cytokines and gene expression changes in peripheral blood mononuclear cells are measured.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Control group: 52 patients with breast cancer are randomly included in the control group, this group is subjected to neoadjuvant chemotherapy (anthracyline base drugs) and prescribed until the patient's re-examination (about 2 months). At the end of 4 courses of chemotherapy (every two weeks), breast ultrasound is performed again to evaluate the treatment response, blood samples of the patients at the beginning and at the end of the study (2 months after the start of the treatment course) were taken in the amount of 7-10 cc and the amount cytokines and gene expression changes are measured in peripheral blood mononuclear cells.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
5 Azar Hospital, Gorgan
**Full name of responsible person**
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### 2

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## Sponsors / Funding sources

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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**
Gorgan 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

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## Person responsible for updating data

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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**
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**
No - There is not 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