

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The Investigation of Prophylactic Effect of StrataXRT Gel on Radiation Therapy Induced Dermatitis in Breast Cancer Patients.

#### Protocol summary

##### Study aim

Introducing a new and effective drug to radiation oncologists in order to prevent radiation-induced skin inflammation in patients with breast cancer

##### Design

Clinical trial with control group, parallel groups, 100 patients, without blindness, randomized according to random numbers obtained from www.random.org.

##### Settings and conduct

The patients referring to the radiation oncology department of Namazi hospital in Shiraz are divided into 2 groups of 50 people. The intervention group, from the first day of radiotherapy, wash twice a day, 6 hours apart, with the water and soap first, and then the StrataXRT gel are applied to the wall of the chest with a thickness of 1-2 mm. The control group only wash the area with water and soap. Both groups are examined on a weekly basis and in the event of grade II dermatitis, they are treated as usual.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with newly diagnosed breast cancer undergoing radical mastectomy and candidate for radiation therapy, no contraindication for radiotherapy, three weeks after chemotherapy, not receiving simultaneously chemotherapy and Herceptin. Exclusion criteria: All patients with history of radiation therapy of breast, Patients with a history of systemic or cutaneous diseases.

##### Intervention groups

Patients are divided into intervention and control groups. The intervention group uses the StrataXRT gel twice daily on the chest wall radiotherapy day after the first day of radiation therapy. The control group will have just daily rinses radiation treatment. Both groups are examined weekly.

##### Main outcome variables

Grading of dermatitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181030041507N1**

Registration date: **2018-12-31, 1397/10/10**

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

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

##### Registration date

2018-12-31, 1397/10/10

##### Registrant information

##### Name

Zahra Eskandari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4352 3347

##### Email address

z.e01365@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Investigation of Prophylactic Effect of StrataXRT Gel on Radiation Therapy Induced Dermatitis in Breast Cancer Patients.

#### Public title

Prophylactic Effect of StrataXRT Gel on Radiation Therapy Induced Dermatitis

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients with newly diagnosed breast cancer undergoing radical mastectomy and candidate for radiation therapy. Signing the informed consent form. No contraindication for radiotherapy. Three weeks after chemotherapy. Not receiving simultaneously chemotherapy and Herceptin.

##### Exclusion criteria:

All patients with history of radiation therapy of breast. A history of systemic or cutaneous diseases such as diabetes mellitus or collagen vascular disease, and concomitant use of wound healing drugs such as systemic steroids.

#### Age

From **18 years** old to **85 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Among patients referring to the radiation oncology department of Namazi hospital in Shiraz, who have breast cancer and undergo radical mastectomy and candidate for radiotherapy, will be randomly underwent radiation therapy, and 100 patients will be randomly placed in two main groups (StrataXRT) or control group according to randomized numbers obtaining from the website : [www.random.org](http://www.random.org)

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

##### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

#### Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

#### Street address

No.216, Alavi Dormitory., 2 Alley., Mollasadra Street.

#### City

Shiraz

#### Province

Fars

#### Postal code

7193613565

#### Approval date

2018-09-30, 1397/07/08

#### Ethics committee reference number

IR.SUMS.MED.REC.1397.240

## Health conditions studied

### 1

#### Description of health condition studied

Radiation Induced Dermatitis in Breast Cancer

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Low Grade Skin Inflammatory Changes

#### Timepoint

Weekly

#### Method of measurement

Direct Observation and Transparent Sheet

## Secondary outcomes

### 1

#### Description

Efficacy of StrataXRT gel

#### Timepoint

Weekly

#### Method of measurement

Examining the patient's medical records.

## Intervention groups

### 1

#### Description

Intervention group: One group of patients from the first day will use the StrataXRT gel twice daily and 5 consecutive days per week for 5-5.5 weeks on radiotherapy area, which has already been identified by the treatment planning system. Patients should wash the radiation site twice daily with water and soap, and then used StrataXRT gel on chest wall with 1-2 mm thickness, and before radiation therapy, to prevent further burns, rinse the area with water and soap. The time interval

between using Strata XRT gel twice per day is six hours. this group are examined weekly and in case of second grade dermatitis, they are treated in both groups of patients. In these cases, dermatitis will be evaluated using the grading scale of acute complications according to the following table. This drug contains compounds: polidimetilsilossani, silossani, alchilmetil siliconi, and the company is manufacturing stratpharma switzerland.

**Category**

Prevention

**2****Description**

Control group: This group is considered as a control and it is also recommended that they daily wash the radiotherapy area, such as the intervention group and examined weekly and in case of second grade dermatitis, they are treated in the groups of patients. In these cases, dermatitis will be evaluated using the grading scale of acute complications according to the following special table.

**Category**

Diagnosis

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Zahra Eskandari

**Street address**

Radiation Therapy Department., Namazi Hospital

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613565

**Phone**

+98 71 3647 4320

**Fax**

+98 71 3647 4320

**Email**

Z\_Eskandari@sums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

**Street address**

Vice Chancellor for Research., Shiraz University of Medical Sciences., Zand Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3230 5410

**Fax**

+98 71 3212 2430

**Email**

Vcrdep@sums.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zahra Eskandari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

No. 216, Alawi student dormitory., 2Alley., Mollasadra St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613565

**Phone**

+98 71 4352 3347

**Fax****Email**

Z.e01365@gmail.com

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Omidvari Shapoor

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Hospital Namazi., Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Phone**

+98 71 3647 4320

**Email**

Omidvari@sums.ac.ir

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Mohammadian Panah

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Hospital Namazi., Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7193711351

**Phone**

+98 71 3647 4320

**Email**

mohpanah@gmail.com

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No More Information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available