

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

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