Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+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 compani 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

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Radiation Therapy Department., Namazi Hospital

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Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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

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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

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

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Professor

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Specialist

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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