Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of dermoline- henna cream with Strata XRT cream onradiodermatitis in breast cancer

Protocol summary

Study aim
effect of dermolin henna cream on radiotherapy dermatitis compare to strata XRT

Design
We examine the cases each week in radiotherapy and after dermatitis grade 2, we give them the creams to use 2 timed a day after treatment.

Settings and conduct
In each group, after grade 2 dermatitis, they should use cream. Imam Hossein Hospital. Radiation oncology department

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Breast cancer women 18-70 years radiotherapy to breast Caes who have breast conservative surgery not mastectomy Exclusion criteria: ulcer or unhealed scar or cellulitis in the field of radiotherapy history of diabetes - renal failure- anemia- hypertension history of collagen vascular disease deformity of chest wall history of chronic skin disease on chest wall breast concurrent chemoradiation history of radiotherapy to breast or chest

Intervention groups
There are two groups. There is no control group. This is a pilot study and due to limited number of Strata XRT cream (20), we can have only 20 cases in each group.

Main outcome variables
Age Dermatitis grade (due to RTOG grading system) Total dose of radiotherapy Dose of radiotherapy when grade 2 dermatitis appears Drug adverse effects pain Itching Burning

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150919024084N2**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **prospective**
Last update: **2022-08-16, 1401/05/25**
Update count: **0**

Registration date
2022-08-16, 1401/05/25

Registrant information

Name
Shaghayegh Kamian

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 912 311 4846

Email address
shkamian@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of dermoline- henna cream with Strata XRT cream onradiodermatitis in breast cancer

Public title
Comparison of the efficacy of dermoline- henna cream with Strata XRT cream on radiodermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1-Breast cancer women 18-70 years radiotherapy to breast Breast conservative surgery
Exclusion criteria:
ulcer or unhealed scar or cellulitis in history of diabetes - renal failure- anemia- hypertension history of collagen vascular disease deformity of chest wall history of chronic skin disease on chest wall and breast concurrent chemoradiation history of radiotherapy to breast or chest

Age
From **18 years** old to **70 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This is a pilot study with 20 cases in each group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Radiation oncology department- Imam Hossein hospital- Shahid Madani St.- Imam Hossein Sq.
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2022-05-30, 1401/03/09
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.086

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50.9
ICD-10 code description
Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description
radiation dermatitis
Timepoint
from day 1 of radiotherapy till the end of it, weekly
Method of measurement
(Radiation Oncology Grading Group) RTOG grading system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group one: There are 20 cases in this group. We give the patients the cream that its base is dermolin henna when there is dermatitis grade 2 in the the field of radiotherapy.
Category
Treatment - Drugs

2

Description
Intervention group 2: There are 20 cases in the second group. We give the patients Starat XRT cream when there is dermatitis grade 2 in the the field of radiotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Shaghayegh Kamian
Street address
Shahid Madani
City
Tehran
Province
Tehran

Postal code
1617763141
Phone
+98 21 7343 2614
Email
shkamian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Besides Taleghani Hospital, Aarabi St., Velenjak Ave.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
shkamian@sbmu.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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shaghayegh kamian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Imam Hossein Hospital, Shahid Madani St., Imam Hossein Sq.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 2614
Email
shkamian@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shaghayegh Kamian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Sahid Madani
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 2416
Email
shkamian@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shaghayegh Kamian
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Shahid Madani
City
Tehran
Province
Tehran
Postal code
1617763141
Phone

+98 21 7343 2614
Email
shkamian@sbmu.ac.ir

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
on demand of journal for publication
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
Undecided - It is not yet known if there will be 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
Not applicable