Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The assessment of Avena Sativa cream efficacy on skin reactions caused by radiotherapy in patients with breast cancer.

Protocol summary

Summary

Objective: The assessment of Avena Sativa cream efficacy on skin reactions caused by radiotherapy in patients with breast cancer. Interventions: After obtaining informed consent from the patient, at the first time of beginning radiotherapy we will recommend to patients use the cream which prepared from oat extract, three times a day each 8 hours daily (TDS), in the radiotherapy area, amount of one finger (FTU) will be applied uniformly with the index finger (considerably in different patients based on the extent of the lesion, this unit can be doubled) and for 3 hours, they must avoid washing the area. In the control group patients will use placebo (extract-free cream base). Then, The skin reactions such as tenderness, pain, itching, burning sensation, erythema, dry desquamation and the grade of dermatitis caused by radiotherapy will be examined at the intervals of 10 days after initiation of treatment (start of the major erythema reaction), 28 days after initiation of treatment (start of dry desquamation), on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up. Then the data will be collected with RTOG questionnaire (to determine the grade of radio dermatitis) and researcher-made questionnaire which its validity and reliability will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311015987N8**
Registration date: **2014-08-05, 1393/05/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-05, 1393/05/14

Registrant information

Name
Shahrzad Ghiyasvandian
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of Avena Sativa cream efficacy on skin reactions caused by radiotherapy in patients with breast cancer.

Public title

The Effect of Oat Cream on skin reaction caused by radiotherapy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women with breast cancer; Without

any skin lesion. Exclusion criteria: Patients with uncontrolled diabetes; Acquired immunodeficiency syndrome; A history of allergy to medicinal plants.

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy Tehran University of Medical Sciences

Street address
sixth floor of the University Center, Qods St, Keshavarz Blvd. Tel: 88987382 - Fax: 88989664

City
Tehran

Postal code

Approval date
2014-05-19, 1393/02/29

Ethics committee reference number
130/405

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code
C50.9

ICD-10 code description
Malignant Neoplasm of Breast

Primary outcomes

1

Description
The grade of skin reaction caused by radioytherapy

Timepoint
At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement
Using the RTOG questionnaire and researcher-made questionnaire.

2

Description
Erythema

Timepoint
At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up.

Method of measurement
Using the RTOG questionnaire and researcher-made questionnaire.

3

Description
Dry desquamation

Timepoint
At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up.

Method of measurement
Using the RTOG questionnaire and researcher-made questionnaire.

4

Description
Itching

Timepoint
At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement
Ask the patient and using a researcher-made questionnaire

5

Description
Burning sensation

Timepoint

At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement

Ask the patient and using a researcher-made questionnaire

6

Description

Changes in daily activities

Timepoint

At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement

Ask the patient

7

Description

Tenderness

Timepoint

At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement

Ask the patient

Secondary outcomes

1

Description

Patchy and Distribution Moist Desquamation

Timepoint

At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement

Examination by a physician

2

Description

Drainage, Infection, Cellulitis

Timepoint

At the intervals of 10 days after initiation of treatment , 28 days after initiation of treatment, on the last day of radiotherapy and after that in two times with one week interval, after the end of radiotherapy participants will be followed up

Method of measurement

Examination by a physician

Intervention groups

1

Description

At the first time of beginning radiotherapy we will recommend to patients use the cream which prepared from oat extract, three times a day each 8 hours daily (TDS), in the radiotherapy area, amount of one finger (FTU) will be applied uniformly with the index finger (considerably in different patients based on the extent of the lesion, this unit can be doubled) and for 3 hours, they must avoid washing the area.

Category

Treatment - Drugs

2

Description

In the control group patients will use placebo (extract-free cream base).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ramezanzade of Radiotherapy center in Yazd

Full name of responsible person

Antikchi Mahnaz, MSc student in Medical-Surgical Nursing The Tehran University,Iran

Street address

Shahid Motahari Avenue in front of the Rohaniyoon gas station, YAZD

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Tehran University of Medical Science

Street address

sixth floor of the University Center, Qods St, Keshavarz Blvd. Tel: 88987382 - Fax: 88989664

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences,School of Nursing and Midwifery

Full name of responsible person

Shahrzad ghiyasvandiyan

Position

Vice-Dean for Education Assistant Professor, Ph.D. in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty