

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

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

#### Protocol summary

2014-08-05, 1393/05/14

##### 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.

##### Registrant information

###### Name

Shahrzad Ghiasvandian

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6692 7171

###### Email address

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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

#### 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

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 radiotherapy

#### **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

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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 ghyasvandian

**Position**

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

**Other areas of specialty/work**

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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*