

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of German chamomile(*Matricaria recutita* L.) extract in the prevention of acute radiation dermatitis in the patients with breast cancer

#### Protocol summary

##### Summary

Although acute radiation dermatitis is a common side-effect of radiotherapy, currently there is no general consensus about its prevention or treatment of choice. In this study, we aimed to measure the impact of Chamomile in prevention of radiation dermatitis. This study is triple blind randomized placebo- controlled trial. The sample size in each group, 30 cases were considered. Patients were randomly divided to either drug or placebo groups . Cream will be used three times daily for 6 consecutive weeks. Patients on days 3, 6, 9, 12, 15, 18, 21, 24 and 2 weeks after treatment are examined and the incidence and severity of dermatitis visited the RTOG criteria will be reported.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107207074N1**

Registration date: **2011-10-05, 1390/07/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-10-05, 1390/07/13

##### Registrant information

##### Name

Fatemeh Jourkesh

##### Name of organization / entity

Nursing Midwifery Jundishapur

##### Country

Iran (Islamic Republic of)

##### Phone

+98 78 1224 0960

##### Email address

jourkesh.f@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Jondi Shapour University of Medical Sciences

##### Expected recruitment start date

2011-02-20, 1389/12/01

##### Expected recruitment end date

2011-07-23, 1390/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of German chamomile(*Matricaria recutita* L.) extract in the prevention of acute radiation dermatitis in the patients with breast cancer

##### Public title

The effect of chamomile extract for acute radiation dermatitis

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria; Adults over 18 years; breast cancer diagnosis in a Syth is approved by the oncologist; Patients who underwent a radical mastectomy and breast have been; Not having a mental illness; not using the drug topically on affected area of acute dermatitis; a chronic skin disease such as pemphigus and no collagen vascular disease; the disease weakens the immune system; a lack of diabetes; Old burn scars in the area of radiation; no use in patients bolus; not receiving

concurrent chemotherapy with radiation; the lack of sensitivity to drug testing patch; 5000 cGy total dose of radiation; the depth of the cm 7.5-9.5; mass physical between 19.8 to 26; is able to communicate out of this situation; not wanting to continue the intervention; surgery, infection and bleeding at the time of the study; the incidence of drug allergy

#### Age

From **18 years** old to **100 years** old

#### 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)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Joundi Shapor University

###### Street address

Joundi Shapor University, Golestan street, Ahwaz

###### City

Ahwaz

###### Postal code

##### Approval date

2011-02-20, 1389/12/01

##### Ethics committee reference number

Eth155

### Health conditions studied

#### 1

##### Description of health condition studied

Radiation acute dermatitis

##### ICD-10 code

L24

##### ICD-10 code description

Irritant contact dermatitis

#### 2

##### Description of health condition studied

Breast cancer

##### ICD-10 code

C50

##### ICD-10 code description

Malignant neoplasm of breast

### Primary outcomes

#### 1

##### Description

Intensity of radiation acute dermatitis

##### Timepoint

3, 6, 9, 12, 15, 18, 21, 24 days and 2 week after completion of treatment

##### Method of measurement

RTOG criteria based on measurements that can be graded from 0 to 4

### Secondary outcomes

#### 1

##### Description

Drug allergy

##### Timepoint

During treatment

##### Method of measurement

Czech list

### Intervention groups

#### 1

##### Description

Chamomile extract is prescribed in the Basic Cold Cream, 4% in the cream, 3 times a day on the first day of radiation therapy to radiation treatment two weeks after

##### Category

Prevention

#### 2

##### Description

Control: placebo administered in combination with the base color and allowed Cold Cream orally 3 times a day on the first day of radiation therapy to radiation treatment two weeks after

##### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Radiotherapy Department, Golestan Hospital, Ahwaz

###### Full name of responsible person

Fatemeh Jourkesh

**Street address**

Golestan Hospital, Golestan street, Ahwaz

**City**

Ahwaz

jourkesh.f@ajums.ac.ir

**Web page address**

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Ahwaz University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Fegghi

**Street address**

Nursing and Midwifery College, Ahwaz Jondi Shapur University of Medical Sciences, Golestan street, Ahwaz

**City**

Ahwaz.

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Ahwaz University of Medical Sciences

**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**

University of Medical Sciences

**Full name of responsible person**

Fatemeh Jourkesh

**Position**

Master Nursing

**Other areas of specialty/work**

**Street address**

Nursing and Midwifery College, Ahwaz Jondi Shapur University of Medical Av, Golestan street, Ahwaz

**City**

Ahwaz

**Postal code**

**Phone**

+98 78 1224 0960

**Fax**

**Email**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahwaz Jondi Shapur University of Medical Sciences

**Full name of responsible person**

Fatemeh Jourkesh

**Position**

Master Nursing

**Other areas of specialty/work**

**Street address**

Ahwaz Jondi Shapur University of Medical Sciences, Golestan street, Ahwaz

**City**

Ahwaz

**Postal code**

**Phone**

+98 78 1224 0960

**Fax**

**Email**

jourkesh.f@ajums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Jondi Shapour Ahwaz University

**Full name of responsible person**

Fatemeh Jourkesh

**Position**

Master Nursing

**Other areas of specialty/work**

**Street address**

Ahwaz Jondi Shapur University of Medical Sciences, Golestan street, Ahwaz

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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*