Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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 Feghhi

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

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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