Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of topical use of Chicory root extract gel on the incidence and severity of radiation therapy-induced dermatitis in breast cancer patients.

Protocol summary

Study aim
Determining the effect of topical use of chicory root extract gel on the incidence and severity of radiation therapy-induced dermatitis in breast cancer patients

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 44 patients. (Sealed Envelope software, London, UK) was used for randomization.

Settings and conduct
This study will be performed in the radiotherapy ward of yasrebi Hospital in Kashan-Iran. Patients with random entry criteria will receive chicory gel and placebo. The gel will be used twice a day from the beginning of radiation therapy until the end of the radiation therapy period (one month) in the position under radiation therapy. Patients, researchers, statistical analysts and treatment team will not be aware of the patient group.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study, giving informed consent؛ Breast cancer based on the diagnosis of an oncologist؛ Lack of known allergy to chicory plant and medical contraindication to chicory extract؛ Absence of ulcers or unhealed scars at the site of radiation therapy؛ No history of radiation therapy at the current treatment site؛ No history of breast reconstruction (prosthesis) and concomitant chemotherapy

Intervention groups
Patients will not be deprived of any routine care and treatment by participating in the study. Both intervention and placebo groups will use gel-containing tubes topically twice a day, from the first day of radiation therapy to one month (until the end of radiation therapy). Gel tubes are coded for blinding. Patients in the intervention group will use 3% chicory root gel extract tube and placebo group will use placebo gel tube which is without active ingredient. Gel tubes are matched in appearance.

Main outcome variables
Incidence of radiation-induced dermatitis؛ Severity of radiation-induced dermatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220601055055N1**
Registration date: **2022-07-02, 1401/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-02, 1401/04/11**
Update count: **0**

Registration date
2022-07-02, 1401/04/11

Registrant information

Name
Fatemeh Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-01, 1401/04/10

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical use of Chicory root extract gel on the incidence and severity of radiation therapy-induced dermatitis in breast cancer patients.

Public title

The effect of Chicory root extract on radiation therapy-induced dermatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency to participate in the study Giving informed consent Having breast cancer based on the diagnosis of an oncologist

Exclusion criteria:

known allergy to chicory plant and medical contraindication to chicory extract Existence of an ulcerated ulcer or scar at the site of radiation therapy History of previous radiation therapy at the current treatment site History of breast reconstruction (prosthesis) Simultaneous chemotherapy

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are consecutively entered into the study and coded, then they are randomly divided into 11 blocks of 4 using a (Sealed Envelope software program, London, UK) . In each block, two people will be randomly assigned to the intervention group and two people to the placebo group. The randomization process is done by the first researcher. The second researcher, who is involved in the daily sampling and evaluation of patients, is blinded to the placement of the individual in the intervention or placebo group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The first executor uses a software program (Sealed Envelope software, London, UK) to randomly place people based on 4 blocks in two intervention groups (22 people) and placebo (22 people) and a list of codes Creates a dedicated and randomly assigns each patient to the intervention group and placebo. The first performer of the study, according to the code assigned to the patient, delivers 100 g tubes containing chicory root extract or placebo gel, which is encoded, to the second performer to provide to the patients. The second executor has been blinded to the allocation of individuals in study groups and drug tubes. Due to the coding of the evaluator, the treatment team and the patient are blinded to being in the desired group. Also, the statistical analyzer will perform the analysis according to the codes without knowing the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Researches, Faculties of Nursing and Midwifery, Health and Allied Med

Street address

Parastar Blvd., Ghotb Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2022-05-16, 1401/02/26

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1401.017

Health conditions studied

1

Description of health condition studied

Radiodermatitis

ICD-10 code

L58.0

ICD-10 code description

Acute radiodermatitis

Primary outcomes

1

Description

Radiodermatitis score in Radiation Therapy Oncology Group Scale (RTOG Scale)

Timepoint

Daily (from the beginning of the study to the end of radiation therapy)

Method of measurement

Radiation Therapy Oncology Group Scale (RTOG Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the first day of radiation therapy to the end of it (for one month), the intervention group will use 3% chicory root extract gel topically twice a day topically in the area undergoing radiation therapy.Tubes of 100 g containing the mentioned gel have been prepared by the Medicinal Plants Research Center of Shahrekord University of Medical Sciences.

Category

Prevention

2

Description

Control group: In the control group, from the first day of radiation therapy to the end of it (for one month), twice a day, placebo gel, which has similar appearance properties to chicory root extract gel; They will be used topically in the area under radiation therapy. Tubes of 100 g containing the mentioned gel have been prepared by the Medicinal Plants Research Center of Shahrekord University of Medical Sciences.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasrebi Hospital

Full name of responsible person

Mostafa Sarvizadeh

Street address

Parastar Blvd., Ghotb Ravandi Blvd

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Email

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Web page address

http://yasrebihospital.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

Kashan University of Medical Sciences, Ravand Blvd., Kashan, Iran Postal Code: 8715988141

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http://research.kaums.ac.ir/Default.aspx?PageID=58

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Jafari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position
Assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available