Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effects of oral zinc sulfate on prevention and treatment of radiation induced acute dermatitis in patients with breast cancer

Protocol summary

Study aim

Determining effect of oral zinc sulfate on the prevention and treatment of radiotherapy-induced acute dermatitis in patients with breast cancer

Design

study include 150 patients who will be randomly divided into 3 groups A, B, C using a table of random numbers. The drugs are similar in appearance and method of use and the study is double-blind . method of blinding : none of the patients, physician and statistical analyst will be aware of the type of intervention performed.

Settings and conduct

afzalipour hospital, radiotherapy center

Participants/Inclusion and exclusion criteria

INCLUSION: Patients at least 18 years old, KPS score more than 70 , non-inflammatory breast cancer who candidates for whole breast RT exclusion: history of radiation to the breast or chest, inflammatory breast lesion , reconstructive breast surgery, bilateral breast cancer, diabetes, and patients taking antioxidant supplements or a history of known gastrointestinal disease will not be included . Other exclusion criteria include active connective tissue disease, scarring without healing due to previous surgery. Before entering to the study, informed written consent will be obtained from them. If patients are not satisfied will be excluded from the study

Intervention groups

Group A: This group will be treated with a dose of 220 mg oral zinc sulfate (Alhavipharm), 3 times a day every 8 hours throughout the treatment. Group B: In this group, they will receive 220 mg oral zinc sulfate (Alhavipharm) twice a day and one placebo, every 8 hours. Group C: This group of patients is the control group and will receive placebo (Behsaz Arshian Daroo) for the whole time, which is completely similar in appearance but lacks the active ingredient of zinc sulfate capsule 3 times a day every 8 hours.

Main outcome variables

Degree of dermatitis Need for narcotics to reduce burn pain during treatment dermatitis site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047857N1**
Registration date: **2021-08-26, 1400/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-26, 1400/06/04**
Update count: **0**

Registration date

2021-08-26, 1400/06/04

Registrant information

Name

masumeh nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7236

Email address

nourim861@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-10, 1400/02/20

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of oral zinc sulfate on prevention and treatment of radiation induced acute dermatitis in patients with breast cancer

Public title
The effect of oral zinc sulfate on radiotherapy-induced acute dermatitis in breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with non-inflammatory breast cancer Undergone surgery and chemotherapy Candidates for whole breast radiotherapy

Exclusion criteria:
Dissatisfaction with participating in the study Existence of contraindications to radiation therapy

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
For the two-way blinding process, after selecting patients for radiotherapy, they are told that before radiotherapy, a drug is used orally for them , which has no side effects in previous studies and can reduce the side effects of radiotherapy. Finally, we ask the person selected for this job to bring the medicine card. The drug can be a placebo or zinc sulfate. The researcher is not aware of the nature of the drug. Each patient and the drug used for him are identified by the same number. For example, patient number 8 and drug number 8.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipour Educational and Medical Center

City
Kerman

Province
Kerman

Postal code
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Approval date
2020-06-09, 1399/03/20

Ethics committee reference number
IR.KMU.REC.1399.203

Health conditions studied

1

Description of health condition studied
acute dermatitis to breast cancer radiation therapy

ICD-10 code
L58

ICD-10 code description
Radiodermatitis

Primary outcomes

1

Description
Degree of dermatitis

Timepoint
In the first treatment session and weekly after every 5 sessions and then at the end of treatment sessions and then 1 month and then 3 months after radiotherapy

Method of measurement
The dermatitis grade will be based on the following RTOG criteria: Grade 1: Erythema and brief reddening and follicular or fading of the skin, dry scaling of the skin, reduction of skin perspiration Grade 2: Painful or glowing erythema of the skin, patchy scaling Wet, brief skin edema Grade 3: Wet scaling of the skin in areas other than skin folds, skin edema Grade 4: Wounds, necrosis, bleeding at each visit / burn site (supraclavicular, axilla, submamillaria, internal Mammillaria) / Cases in which dermatitis leads to discontinuation of treatment or pain resulting from drug use

2

Description
Need for narcotic

Timepoint
In the first treatment session and weekly after every 5 sessions and then at the end of treatment sessions and then 1 month and then 3 months after radiotherapy

Method of measurement
Frequent need for analgesia

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will be treated daily with a dose of 220 mg of zinc sulfate (containing pharmacy) equivalent to 50 mg of elemental zinc, 3 times a day every 8 hours (total zinc intake 150 mg) throughout the treatment.
Category
Treatment - Drugs

2

Description
Intervention group: In this group, they will receive 220 mg (pharmaceutical content) twice and a placebo (Behsaz Arshian Daroo) twice, which will be every 8 hours (the amount of zinc received will be 100 mg in total).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Masoumeh Nouri
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Afzalipour hospital, Talegani Blvd, Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Masoumeh Nouri
Position
Resident
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Person responsible for updating data

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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