

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

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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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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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

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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