Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Topical vitamin E and zinc oxide versus zinc oxide in treatment of radiation dermatitis: a double-blind clinical trial

Protocol summary

Study aim
Investigating the effect of vitamin E in the treatment of radiotherapy dermatitis
Design
A controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 56 patients. For randomization, the block random assignment method was used.
Settings and conduct
This project is carried out in Shahid Ramzanzadeh center in Yazd. Patients in two groups of 28 people use zinc oxide cream and vitamin E or zinc oxide twice a day for 4 weeks.
Participants/Inclusion and exclusion criteria
Patients with radiotherapy-induced dermatitis who do not have severe skin disease or systemic disease
Intervention groups
In order to investigate the effectiveness of zinc oxide and topical vitamin E in radiotherapy dermatitis, we gave zinc oxide and topical vitamin E to a group of 28 people and zinc oxide to a group of 28 people.
Main outcome variables
Erythema severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181208041882N14**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **retrospective**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**
Registration date
2023-10-16, 1402/07/24

Registrant information
Name
behrooz heydari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2023-06-21, 1402/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Topical vitamin E and zinc oxide versus zinc oxide in treatment of radiation dermatitis: a double-blind clinical trial

Public title
The effect of vitamin E in the treatment of radiotherapy dermatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with grade 1 to 2 skin dermatitis caused by radiotherapy Patients aged 18 to 65 years
Exclusion criteria:
Patients with skin disease hypersensitivity to vitamin E or

zinc oxide Severe systemic disease such as uncontrolled diabetes

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 56 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 12 blocks of 5 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 56 is in 12 blocks of five in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 56.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients, the clinical caregiver and the outcome assessor were not aware of the type of medication the patients received. The patients in the two groups received the medications in the same packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2018-01-10, 1396/10/20

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.244

Health conditions studied

1

Description of health condition studied

Dermatitis caused by breast radiation therapy

ICD-10 code

L58

ICD-10 code description

Radiodermatitis

Primary outcomes

1

Description

Intensity of redness

Timepoint

Weeks 0, 1, 2, 3, 4

Method of measurement

RTOG standard scale

2

Description

Itching intensity

Timepoint

Weeks 0,1,2,3,4

Method of measurement

Based on visual analog scale

3

Description

Intensity of burning

Timepoint

Weeks 0,1,2,3,4

Method of measurement

Based on visual analog scale

4

Description

Intensity of pain

Timepoint

Weeks 0,1,2,3,4

Method of measurement

Based on visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patient receives topical ointment of vitamin E 18% and zinc oxide 20% (manufactured in Yazd Faculty of Pharmacy) twice daily from the first day of radiation therapy for four weeks.
Category
Treatment - Drugs

2

Description
Control group: The patient receives 20% zinc oxide topical ointment (manufactured in Yazd Faculty of Pharmacy) twice a day from the first day of radiation therapy for four weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ramezanzadeh Radiotherapy Center, Yazd
Full name of responsible person
Masood Shabani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abarghouei
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Shahid Sadoughi University of medical sciences, Shohadaye Gomnan Blvd, Alem Sq
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abargouei@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Behrooz Heydari
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After nonrecognition, all data can be share
When the data will become available and for how long
6 months after publication
To whom data/document is available
All of researchers
Under which criteria data/document could be used
nothing
From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir
What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.
Comments