

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8699

Email address

b.heydari@ssu.ac.ir

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 Gornam 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

Street address

Shahid Mottahari Street, Azadi Sq

City

Yazd

Province

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8917657961

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shabanimasood@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abarghouei

Street address

Shahid Sadoughi University of medical sciences,
Shohadaye Gornan Blvd, Alem Sq

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Email

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data**Contact****Name of organization / entity**

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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