

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of 2% curcumin gel effectiveness in prophylaxis of radiation dermatitis

Protocol summary

Study aim

Evaluation of 2% curcumin gel effectiveness in prophylaxis of radiation dermatitis

Design

Placebo-controlled double-blind clinical trial with parallel groups of 52 patients

Settings and conduct

The study was conducted at the Shahid Ramezanzadeh Radiation Therapy Center in Yazd. A total of 60 female patients with breast cancer who were considered to be the initiators of radiation therapy were randomly selected and entered one of the two study groups rather than one of the drug groups. (Curcumin gel should be 2% and placebo gel). The patient evaluating the outcome and the clinical caregivers were unaware of the type of drug. The patients used the gel twice a day for four weeks from the first day of radiation therapy. Information on the severity of rubella, the severity of pruritus, the severity of the burn, and the severity of the pain were recorded at the opposite time (beginning of treatment in the first week, second week, third week, and fourth week after treatment).

Participants/Inclusion and exclusion criteria

Women 18 to 65 years old to get started Breast radiation therapy has been referred to Shahid Ramezanzadeh Radiotherapy Center in Yazd

Intervention groups

Intervention group: Patients receiving 2% curcumin gel.
Control group: Patients receiving placebo gel

Main outcome variables

Curcumin gel 2% was able to reduce the severity of burning and pain in patients compared to placebo gel, but there was no difference between the curcumin and placebo groups in terms of itching severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N3**

Registration date: **2020-11-06, 1399/08/16**

Registration timing: **retrospective**

Last update: **2020-11-06, 1399/08/16**

Update count: **0**

Registration date

2020-11-06, 1399/08/16

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

2019-06-16, 1398/03/26

Expected recruitment end date

2019-10-27, 1398/08/05

Actual recruitment start date

2019-06-15, 1398/03/25

Actual recruitment end date

2019-11-16, 1398/08/25

Trial completion date

2019-11-16, 1398/08/25

Scientific title

Evaluation of 2% curcumin gel effectiveness in prophylaxis of radiation dermatitis

Public title

Evaluation of curcumin gel effectiveness in prophylaxis of radiation dermatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women 18 to 65 years old to get started breast radiation therapy has been referred to Shahid Ramezanzadeh Radiotherapy Center in Yazd

Exclusion criteria:

People with skin diseases People who are allergic to curcumin People with severe systemic diseases such as uncontrolled diabetes

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method was used. Patients were randomly assigned to two groups by using Random.org site

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, clinical caregivers and outcome assessors were unaware of the type of medication patients were receiving. Patients in both groups received the medication in the same package.

Placebo

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 sciences
Shohadaye Gornam Blve Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2019-02-06, 1397/11/17

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.078

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

The severity of the redness begins with treatment
Redness intensity in the first week Redness intensity in the second week Redness intensity in the third week and redness intensity in the fourth week after starting treatment

Method of measurement

RTOG standard scale

2

Description

Itching intensity

Timepoint

The severity of itching begins treatment Severity of itching in the first week Severity of itching in the second week Severity of itching in the third week and severity of itching in the fourth week after starting treatment

Method of measurement

Based on a question from the patient

3

Description

Intensity of burning

Timepoint

Severe onset of burning of treatment of severity of burning in the first week, severity of burning in the second week, severity of burning in the third week, and severity of burning in the fourth week after starting treatment

Method of measurement

Based on a question from the patient

4

Description

Intensity of pain

Timepoint

Intensity of pain Initiation of treatment Intensity of pain
The first week Pain intensity in the second week Pain
intensity in the third week and pain intensity in the
fourth week after starting treatment

Method of measurement

Based on a question from the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Curcumin gel 2% twice daily from the
first day Radiation therapy The patient receives one of
the same gels topically for four weeks. Made in Yazd
University of Medical Sciences

Category

Prevention

2

Description

Control group: Placebo gel twice daily from the first day
Radiation therapy The patient receives one of the same
gels topically for four weeks. Made in Yazd University of
Medical Sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ramezanzadeh Radiotherapy Center, Yazd

Full name of responsible person

Masood Shabani

Street address

Yazd Azadi Sq Shahid Mottahari Street

City

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Province

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8917657961

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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b.heydari@ssu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

دانشگاه علوم پزشکی یزد

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

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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

Dr.Behrooz Heydari email :b.heydari@ssu.ac.ir

What processes are involved for a request to access data/document

Request your informationby email :The data will be sent after a week

Comments