

# 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

Yazd

##### Province

Yazd

##### Postal code

8917657961

##### Phone

+98 35 3725 1171

##### Email

shabanimasood@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Shahid Sadoughi University of medical sciences  
Shohadaye Gornan Blvd Alem Sq

##### City

Yazd

##### Province

Yazd

##### Postal code

8915173149

##### Phone

+98 35 3820 3410

##### Email

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

##### Street address

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Shohadaye Gornam Blv Alem Sq

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**Email**  
b.heydari@ssu.ac.ir

## Person responsible for scientific 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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Shahid Sadoughi University of medical sciences  
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**Email**  
b.heydari@ssu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences

**Full name of responsible person**  
Behrooz Heydari

**Position**  
Assistant professor

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### Email

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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