Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Manufacture of propranolol 3% gel and comparing it with placebo in the prevention of radiotherapy induced dermatitis in breast cancer patients; A double-blind clinical trial

Protocol summary

Study aim

investigating effect of topical propranolol 3% product in preventing radiotherapy induced dermatitis in breast cancer patients; If a topical product can reduce dermatitis in patients undergoing radiotherapy, it will be recommended as an adjunctive treatment to prevent radiotherapy-induced dermatitis.

Design

A double-blind, placebo-controlled, randomized, phase II clinical trial on 56 patients. For randomization, a random sequence was generated using the simple random assignment method using PASS 2021 software.

Settings and conduct

Individuals will be selected to participate in the study from among those referred to Shahid Ramezanzadeh Radiation Therapy Center and will be included in the study if they consent. The blinding process will be performed for the radiation oncologist, and the treatment response evaluator. The radiotherapy dose is 50-60 Gy, given 5 days a week. Patients are told to apply a thin layer of the gel twice a day, two hours before and after radiotherapy.

Participants/Inclusion and exclusion criteria

inclusion criteria: People 18 years and older; Patients who have not had mastectomy surgery. Radiotherapy recipient with a maximum dose of 60 Gy in 200 cGy fractions; exclusion criteria: People with known allergies or contraindications to beta-blockers; Unwillingness to sign the consent form; Inflammatory metastatic carcinoma; Concomitant use of other antioxidant drugs; Connective tissue diseases or chronic skin disease

Intervention groups

Patients are told to apply a thin layer of the propranolol 3% gel(intervention group) or placebo (control group) twice a day for at least two hours before and after radiotherapy.

Main outcome variables

the grade of ARD according to RTOG/EORTC and CTCAE version 5; the quality of life according to the Skindex16 (SD-16) questionnaire; the highest ARD recorded during the study; the time to the first RID.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190425043368N4**
Registration date: **2026-05-23, 1405/03/02**
Registration timing: **prospective**

Last update: **2026-05-23, 1405/03/02**
Update count: **0**

Registration date

2026-05-23, 1405/03/02

Registrant information

Name

Mahtabalsadat Mirjalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3229 3845

Email address

mahtab.mirjalili@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-24, 1405/03/03

Expected recruitment end date

2027-02-15, 1405/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Manufacture of propranolol 3% gel and comparing it with placebo in the prevention of radiotherapy induced dermatitis in breast cancer patients; A double-blind clinical trial

Public title

Manufacture of propranolol 3% gel and comparing it with placebo in the prevention of radiotherapy induced dermatitis in breast cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pathological diagnosis of breast cancer Patients who have not had their entire breast removed Radiotherapy recipient with a maximum dose of 60 Gy in 200 cGy fractions

Exclusion criteria:

People with known allergies or contraindications to beta-blockers Unwillingness to sign the consent form Inflammatory metastatic carcinoma Concomitant use of other antioxidant drugs Connective tissue diseases or chronic skin disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Randomization unit: individual Randomization tool: PASS 2021 software How to create a random sequence: We generate a random sequence using the simple random assignment method. The software output is an Excel file containing a sequence of numbers from one to 56 and a unique code for the research units. Eligible individuals are numbered from 1 to 56 and assigned to an intervention group (A or B). The first eligible individual to attend is assigned number 1, the second individual is assigned number 2, and so on, up to 56 patients in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants and the principal investigator and clinical outcome assessor will be blinded to this study. The gels will be delivered to the patients by a non-researcher in this study, and the patients list will remain with him/her until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahid sadoughi university of medical sciences

Street address

School of Pharmacy, Shahid Sadoughi University of Medical Sciences Campus, Shohada-ye Gomnam Boulevard, Alem Square

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2025-02-23, 1403/12/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1403.318

Health conditions studied

1

Description of health condition studied

Radiotherapy induced dermatitis

ICD-10 code

L58.0

ICD-10 code description

Acute radiodermatitis

Primary outcomes

1

Description

Acute radiation dermatitis (ARD) grade

Timepoint

Weekly for up to 6 weeks

Method of measurement

Based on Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC) and Common Terminology Criteria for Adverse Events (CTCAE) version 5

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of 3% Propranolol Gel. Propranolol hydrochloride powder was obtained from Daroupakhsh Pharmaceutical Chemical Company and the gels are made weekly in the pharmaceutical laboratory of Yazd Faculty of Pharmacy. How to use the gel: Apply topically to the area to be treated 2 hours before radiation therapy, wear clothes after the gel dries. Also use 2 hours after radiation therapy.To be used throughout the entire course of radiation therapy and only on the days when radiation therapy is performed. Store in the refrigerator.

Category

Prevention

2

Description

Control group: They receive a placebo gel, this gel does not contain propranolol hydrochloride, but in terms of other ingredients it is identical to the gel received by the intervention group. The placebo gel is also made in the pharmaceutical laboratory of the Faculty of Pharmacy of Yazd, and its use and storage method is the same as the 3% propranolol gel.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ramezanzadeh Radiotherapy Center, Yazd

Full name of responsible person
Fatemeh Khalighi

Street address
Qasemabad, Alam Square, University of Medical Sciences Campus, Tubi Girls' Dormitory

City
Yazd

Province
Yazd

Postal code
8915173143

Phone
+98 916 494 4880

Email
mobina1680@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr.Mohsen Nabi Meybodi

Street address
Alem Square, Shohadaye Gomnam Boulevard, Shahid Sadoughi University of Medical Sciences

City
Yazd

Province
Yazd

Postal code
8916978477

Phone
+98 35 3724 0171

Email
info@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
Mahtabalsadat Mirjalili

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Shahid Sadoughi University of Medical Sciences Campus, Shohada-ye Gomnam Boulevard, Alem Square

City
Yazd

Province
Yazd

Postal code
8915173149

Phone

+98 35 3820 3419

Email

Mahtab.mirjalili@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mahtabalsadat Mirjalili

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Email

Mahtab.mirjalili@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mahtabalsadat Mirjalili

Position

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+98 35 3820 3419

Email

Mahtab.mirjalili@gmail.com

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