

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Topical Timolol Effectiveness for prophylaxy of radiation induced dermatitis in breast cancer patients

Protocol summary

Study aim

Determination of the effect of topical thymol on radiotherapy dermatitis in patients with breast cancer

Design

A total of 64 female patients older than 18 years with positive histology confirmed the diagnosis of invasive and localized breast cancer, who are candidates for adjuvant radiotherapy after surgery (breast conservation surgery or mastectomy). Patients will be randomized according to a table of random numbers. The study is three-blind and the duration of use of the first day of radiotherapy is the last day of receiving radiation.

Settings and conduct

This study is a three-blind study that will be performed at Shahid Ramezanzadeh Radiation Therapy Center in Yazd. Patients, Radiation oncologist and evaluator of the outcome of the intervention will be blinded. How to use the gel from the first day of radiation therapy to the last day of radiation therapy twice Is in the day.

Participants/Inclusion and exclusion criteria

Female patients over the age of 18 with a positive histology confirm the diagnosis of invasive and localized breast cancer, which is a candidate for post-surgery Edgevant radiotherapy (breast conserving surgery or mastectomy).

Intervention groups

Intervention group: receiving 0.5% thymol gel and control group: receiving placebo

Main outcome variables

Patients' skin phototype, radiotherapy-induced skin reaction intensity, scaling intensity, worst pain experienced

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N11**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **retrospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

f.saghafi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Topical Timolol Effectiveness for prophylaxy of radiation induced dermatitis in breast cancer patients

Public title

Topical Timolol Effectiveness for prophylaxy of radiation induced dermatitis in breast cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients older than 18 years with positive histology confirm invasive and localized breast cancer, who are candidates for adjuvant radiotherapy after surgery (breast conserving or mastectomy). Adequate literacy to fill out a consent form, understand the study, use the drug, report pain and possible side effects

Exclusion criteria:

Inflammatory or metastatic carcinoma Extensive skin diseases Connective tissue diseases known sensitivity to beta-antagonist drugs

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using Random allocation software (version 1.0), we generate a random sequence by a simple random allocation method. In this table, we specify from 1 to 64 and each number is assigned to an intervention group (A or B). The first eligible person is referred to as number 1, the second person as number 2, and so on up to 64 patients. To be blind to random allocation, patients are placed in one of the intervention groups (A or B) according to the table by a third person who is unaware of the interventions.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After the gels preparation, the labels A and B are affixed by a third person and the patients, Radiation oncologist and evaluator of this outcome will be blinded to the type of the intervention.

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

Professor Hesabi Blvd, Yazd Province

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2020-07-06, 1399/04/16

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.058

Health conditions studied

1

Description of health condition studied

Radiodermatitis

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Acute Radiation Dermatitis

Timepoint

Weekly during radiotherapy and two weeks after the end of radiotherapy

Method of measurement

Based on the Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer (RTOG / EORTC)

2

Description

moist desquamation

Timepoint

Weekly during radiotherapy and two weeks after the end of radiotherapy

Method of measurement

Based on the Common Terminology Criteria for Adverse Events (CTCAE, version 5.0)

3

Description

The worst pain experienced

Timepoint

once every two weeks

Method of measurement

Based on Dermatology Life Quality Index (DLQI)

4

Description

Patient' skin phototype

Timepoint

Before starting radiotherapy

Method of measurement

Based on the Fitzpatrick skin phototype scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before and after intervention

Method of measurement

According to the questionnaire EORTC QLQ-C30 (version 3)

2

Description

When the complication occurs

Timepoint

From the beginning of the intervention to two weeks after the end of radiotherapy

Method of measurement

Based on the doctor's observation and the person's statements

Intervention groups

1

Description

Intervention group:Topical 0.5% timolol gel is made by the operator in the laboratory. Patients with breast cancer referred to the center Radiation therapy is included in the study. Patients apply the gel twice a day from the first day of radiotherapy to the last day on the radiation receiving area and after two hours the area is washed. In case of grade 2 dermatitis, the drug is discontinued and the patient undergoes routine treatments. but remains in the study until the end of treatment for follow-up.

Category

Prevention

2

Description

Control group:Placebo gel is made by the operator in the laboratory. Patients with breast cancer referred to the center Radiation therapy is included in the study. Patients apply the gel twice a day from the first day of radiotherapy to the last day on the radiation receiving area and after two hours the area is washed. In case of grade 3 dermatitis, the drug is discontinued and the patient undergoes routine treatments. but remains in the study until the end of treatment for follow-up.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ramezanzadeh Radiation Therapy Center

Full name of responsible person

Dr. Massoud Shabani

Street address

Shahid Motahari Street

City

Yazd

Province

Yazd

Postal code

۸۹۱۷۶۵۷۹۶۱

Phone

+98 35 3725 1174

Fax

+98 35 3724 4078

Email

partodarmani@ssu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Massoud Mirzaei

Street address

Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3146 2056

Email

mmirzaei@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

Phone

+98 35 3820 3419

Email

F.saghafi@ssu.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

zahra hakimi

Position

University student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Blvd., Yazd Province, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3419

Email

zahra.hakimi1997@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Saghafi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Blvd., Yazd Province, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۴۹

Phone

+98 35 3820 3419

Email

F.saghafi@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Saghafi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Blvd., Yazd Province, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۴۹

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