Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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 preparement , 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
Ethic's 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
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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
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City
Yazd
Province
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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

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

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Person responsible for scientific inquiries

Contact

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Fatemeh Saghafi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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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