

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Clinical Effects of Boron Based Gel on the Prevention or Restoring of Radiotherapy Dermatitis in Neck, Head and Breast Cancer Patients

Protocol summary

Study aim

Investigating the Clinical Effects of Boron-based Gel on the Remediation and Prevention of Dermatitis and Radiation Traumatic Causes

Design

Intervention group: During each radiation therapy session, 15 minutes before radiotherapy, 3% sodium pentahydrate panteurate will be used. Control group: During each radiotherapy session, 15 minutes before radiotherapy, the gel will be free of any chemical treatments. With 95% confidence, test power of 95% and using G-Power software, the minimum sample size of 89 items in each group was calculated and with a 10% drop, the sample size was increased to 100 cases per group. Clinical randomized and double blind clinical trials will be conducted.

Settings and conduct

100 patients in the head and neck area and 100 patients undergoing radiation therapy should be enrolled in this study. The first group will use 3% sodium pentahydrate sodium in the radiotherapy area before each radiation therapy. And the second group will receive a placebo. Patients will be examined within 25 days of radiotherapy treatment with radiation-induced dermatitis. This research will be carried out in the radiotherapy department of the Martyr Madani Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

Entry: Patients who are admitted to the study are enrolled in the study and have head and neck cancer in the breast, and are between the ages of 18 and 75 years old and have not received radiotherapy before. Exit: Patients with cancer other than head and neck and breast. Patients aged less than 18 and over 75 years old. Pregnant patients.

Intervention groups

During each radiation therapy session, 15 minutes before radiotherapy, 3% sodium glycosolium pentahydrate will

be used.

Main outcome variables

Radiation-induced skin reactions; Group radiation therapy oncology

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042925N1**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

Registration date

2019-04-29, 1398/02/09

Registrant information

Name

Farshad Seyed Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 6436

Email address

fnejad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-05, 1397/11/16

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Clinical Effects of Boron Based Gel on the Prevention or Restoring of Radiotherapy Dermatitis in Neck, Head and Breast Cancer Patients

Public title
Investigating the Clinical Effects of Boron-based Gel on Restorative Dermatoses and Radiation Traumatic Causes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who agree to enroll in the study Patients with head and neck and breast cancer who decide to use radiotherapy to spend time on chemotherapy. Patients older than 18 years of age and below 75 years Patients who have not received radiotherapy before

Exclusion criteria:

Patients with cancer other than head and neck and breast Pregnant patients Patients with dermatitis regardless of cause

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Given the fact that the sample size is the same in both groups, we use the Excel software and the formula = Rand () to randomize and to increase the precision and balance of the samples in the randomization (for any reason Patient will withdraw from the plan) We use several blocks per group. It will also be provided to the physician to cover the allocation of matte envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

A gel that has an active ingredient in boron with a gel that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the gels themselves do not differ in terms of odor and color, and are completely indistinguishable. (This action was taken by the pharmaceutical company). The important point is that the patient is told that the gel used for the patient may be medication or medication. Clinicians and blind patients will be blinded.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz, Azadi St., Golghast St., Central building of Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-02-04, 1397/11/15

Ethics committee reference number

IR.TBZMED.REC.1397.919

Health conditions studied

1

Description of health condition studied

Radiotherapy-induced dermatitis in patients with neck and head and breast cancers

ICD-10 code

L59.8

ICD-10 code description

Other specified disorders of the skin and subcutaneous tissue related to radiation

Primary outcomes

1

Description

RISR

Timepoint

25 days

Method of measurement

FPHS

2

Description

RTOG

Timepoint

25 days

Method of measurement

FPHS

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: During each radiotherapy session, 15 minutes before radiotherapy, the gel will be free of any chemical treatments.

Category

Placebo

2**Description**

Intervention group: During each radiation therapy session, 15 minutes before radiotherapy, 3% sodium will be used for pentahydrate pantoic acid.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Madani Medical & Training Hospital -
Department of Radiotherapy

Full name of responsible person

Farshad Seyednejad

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Tabriz - University Street - Facing the Golbad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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research-vice@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Farshad Seyed Nejad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the data will be shared

When the data will become available and for how long

2020

To whom data/document is available

University researchers and professors

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

via email

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

Request via email

Comments