Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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: uring each radiation therapy session, 15 minutes before radiotherapy, 3% sodium will be used for pentahydrate panteoborate.
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
Street address
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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Golghast Street
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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
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Person responsible for updating data

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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