Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness and safety of Esomeprazole cream in the prevention of acute radiation dermatitis in head and neck cancer patients

Protocol summary

Study aim
Effectiveness and safety of Esomeprazole cream in prevention of acute radiation dermatitis in head and neck cancer patients

Design
This study is a double-blind, randomized, placebo-controlled clinical trial.

Settings and conduct
This study will be performed in the radiotherapy department of Vali'asr Hospital affiliated with ZUMS (Zanjan, Iran). The eligible participants were randomly allocated to receive the Esomeprazole cream or placebo. All applications of the creams will be started on Day 1 of radiotherapy and continued during and for 4 weeks after the completion of radiation. The patients will be advised to apply a thin layer of their allocated cream on the area of skin being irradiated twice a day, at least two hours before and after radiotherapy and during radiotherapy, patients were approached to adhere to skincare recommendations of clinical practice guidelines for the prevention of acute radiation reactions from the MASCC Skin Toxicity Study Group. The patient, the researcher, and the radio-oncologist were not aware of the patients` allocated group.

Participants/Inclusion and exclusion criteria
Patients with age >18 years and histopathologically proven diagnosis of head and neck cancer who were scheduled to receive at least 60 Grays radiotherapy with or without chemotherapy are included in this study. Patients with a history of previous head and neck radiotherapy, generalized skin diseases, connective tissue diseases, unhealed surgical wounds, use of other proton pump inhibitors, and history of allergy to Esomeprazole or other excipients of topical formulations will be excluded from this study.

Intervention groups
Intervention group: Esomeprazole cream Control group: Placebo

Main outcome variables
The primary endpoint is to determine whether the Esomeprazole cream can reduce the incidence of acute radiation dermatitis in comparison to placebo using RTOG/EORTC criteria.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211029052907N1**
Registration date: **2022-01-28, 1400/11/08**
Registration timing: **prospective**

Last update: **2022-01-28, 1400/11/08**
Update count: **0**

Registration date
2022-01-28, 1400/11/08

Registrant information

Name
Monireh Maham

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3347 3635

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m.maham@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness and safety of Esomeprazole cream in the prevention of acute radiation dermatitis in head and neck cancer patients

Public title
Evaluation of Esomeprazole cream effect on prevention of acute radiation dermatitis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with histopathologically proven diagnosis of head and neck cancer Planned to receive radiotherapy with or without chemotherapy at least 60 Grays
Exclusion criteria:
History of previous head and neck radiotherapy Generalized skin diseases Connective tissue diseases Untreated surgical wounds Currently taking proton pump inhibitors History of allergy to Esomeprazole or other topical formulation excipients
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to 2 groups, with the help of a computer-generated random assignment by an independent statistician who was not part of the study team. Allocation will be concealed using sequentially numbered opaque sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients, researchers, and radiooncologist will not be aware of the medication patients are receiving
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committees of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Azadi Square
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2021-12-01, 1400/09/10
Ethics committee reference number
ir.zums.rec.1400.373

Health conditions studied

1

Description of health condition studied
acute radiation dermatitis
ICD-10 code
L58.0
ICD-10 code description
Acute radiodermatitis

Primary outcomes

1

Description
The primary endpoint is to determine whether the Esomeprazole cream can reduce the incidence of acute radiation dermatitis in comparison to placebo.
Timepoint
Patients will be evaluated for acute radiation dermatitis severity weekly after every fifth RT session.
Method of measurement
The severity of acute radiation dermatitis will be scored using the Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer (RTOG/EORTC) criteria based on the clinical presentation.

Secondary outcomes

1

Description
The secondary outcomes are to assess if Esomeprazole cream reduces radiotherapy-induced symptoms such as pain and moist desquamation and improves the skin-related quality of life as compared to placebo
Timepoint
Patients will be evaluated for radiotherapy-induced

symptoms such as pain and moist desquamation weekly after every fifth RT session. The patients will be requested to fill out the Dermatology Life Quality Index (DLQI) form considering their feelings during the past week.

Method of measurement

The size and severity of moist desquamation will be assessed by the Common Terminology Criteria for Adverse Events (CTCAE, version 5.0) criteria based on the clinical presentation. The worst experienced pain will be evaluated using a visual analog scale. The skin-related quality of life of the patients was appraised using the Dermatology Life Quality Index(DLQI) score.

Intervention groups

1

Description

Intervention group: Esomeprazole cream

Category

Prevention

2

Description

Control group: Placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Monireh Maham

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Monireh Maham

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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