

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the radioprotective effects of famotidine in reducing the hematologic complications of esophageal and cardiac cancers chemoradiation.

Protocol summary

Study aim

Determining the effect of Famotidine as a Radio-protector in reducing the blood side effects of chemo-radiotherapy for esophageal and cardiac cancers

Design

Clinical trial with control group, with parallel group, single blind, randomized, phase 3 on 60 patients. Patients will be divided into intervention and control groups using random blocks (volume of 4 blocks each).

Settings and conduct

Thirty patients will receive famotidine tablets at random and 30 will be studied without taking the pill. Each oral tablet of famotidine will be given once a day 4 hours before chemoradiotherapy. Patients will receive 28 sessions of chemoradiotherapy daily, 5 days a week. Acute complications of radiotherapy will be monitored weekly during the radiotherapy period with a weekly CBC diff check, which is routinely checked in all patients undergoing chemoradiotherapy. The tests will be performed in the laboratory of Valiasr Hospital in Zanjan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with non-metastatic esophageal cancer and non-metastatic cardiac cancer aged 30 to 75 years who are candidates for chemo radiotherapy and do not receive PPIs and other H2-blocker antagonists. Exclusion criteria: patients who die during the project. Patients who are unable to continue treatment due to the severity of treatment complications. Patients with kidney disease who are unable to receive famotidine. Need to use PPI family drugs during the treatment process.

Intervention groups

30 patients with esophageal and cardiac cancer receiving famotidine concomitantly with chemo-radiotherapy and 30 patients receiving placebo with concomitant chemo-radiotherapy

Main outcome variables

Hematologic complications of chemoradiotherapy of esophageal and cardiac cancers including lymphocytopenia, granulocytopenia, thrombocytopenia, anemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170728035349N1**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **prospective**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9443

Email address

zhkarimi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the radioprotective effects of famotidine in reducing the hematologic complications of esophageal and cardiac cancers chemoradiation.

Public title

Evaluation of the effect of Famotidine in esophageal and cardiac cancer

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with non-metastatic esophageal cancer and non-metastatic cardiac cancer aged 30 to 75 years who are candidates for radiotherapy and do not receive PPIs and other H2-blocker antagonists. Aged 30 to 75 years old Being candidates for chemo radiotherapy Do not receive PPIs and other H2-blocker antagonists.

Exclusion criteria:

Patients who die during the project. Patients who are unable to continue treatment due to the severity of treatment complications. Patients who are unable to continue treatment due to the severity of treatment complications. Need to use PPI family drugs during the treatment process

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; participants are assigned in study groups by block randomization method. The blocks sample size is 4; two persons in intervention and two persons in control group. Different possible blocks are randomly selected to achieve final sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participant do not know the intervention they receive.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

Street address

Radiotherapy Department, Valiasr Hospital, Sheikh Fazlollah Nouri Highway, Zanjan City

City

Zanjan

Province

Zanjan

Postal code

45139-56183

Approval date

2020-08-03, 1399/05/13

Ethics committee reference number

IR.ZUMS.REC.1399.158

Health conditions studied**1****Description of health condition studied**

Esophageal Cancer

ICD-10 code

C15

ICD-10 code description

Malignant neoplasm of esophagus

2**Description of health condition studied**

Cardia Cancer

ICD-10 code

C16.0

ICD-10 code description

Malignant neoplasm of cardia

Primary outcomes**1****Description**

Blood Complications Chemo Radiotherapy for esophageal and cardiac cancers

Timepoint

Acute blood complications of chemo radiation weekly during radiotherapy with weekly CBC diff check for 5 weeks

Method of measurement

CBC diff blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients, 28 days of famotidine with 28 sessions of radiotherapy

Category

Prevention

2

Description

Control group: 30 patients take placebo for 28 days concurrent with radiotherapy sessions

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Valiaser Hospital

Full name of responsible person

Zhaleh Karimimoghaddam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mazyar Peyda

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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

Zhaleh Karimimoghaddam

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zhaleh Karimimoghaddam
Position
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Latest degree
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Department of Radiotherapy
City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available