

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effectiveness of famotidine as a radioprotector in reducing the mucosal and hematological complications of prostate cancer radiotherapy

Protocol summary

Study aim

Determining the effectiveness of famotidine tablets as a radioprotector in reducing the mucosal and hematological complications of prostate cancer radiotherapy

Design

A clinical trial with a control group, randomized, phase 3 on 50 patients, in which SAS statistical software will be used to generate a random sequence.

Settings and conduct

Place of study: Radiotherapy Department of Imam Reza Hospital, Kermanshah. Study population: 50 patients with prostate cancer. Type of blinding In this study, blinding was not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 30 to 75 years with prostate cancer. Exclusion criteria: lack of consent to participate in the study; Patients with kidney disease that cannot be prescribed famotidine

Intervention groups

Intervention group: 25 patients will receive famotidine tablets (40 mg). Control group: 25 people will also be studied without receiving pills.

Main outcome variables

mucosal damage, lymphocytopenia, granulocytopenia, thrombocytopenia and anemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231121060132N1**

Registration date: **2024-01-16, 1402/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-16, 1402/10/26**

Update count: **0**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

Iman Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3456 9701

Email address

imen691020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-26, 1402/09/05

Expected recruitment end date

2024-07-21, 1403/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of famotidine as a radioprotector in reducing the mucosal and hematological complications of prostate cancer radiotherapy

Public title

The effect of famotidine on reducing the side effects of prostate cancer radiotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 30 to 75 with prostate cancer candidates for radiotherapy Do not receive PPI drugs and other H2 antagonist drugs

Exclusion criteria:
Lack of consent to participate in the study Patients with kidney disease that cannot be prescribed famotidine

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

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment to intervention and control groups, block randomization using blocks of size four in which two people will be in the intervention group and two people in the control group. Possible quadruple blocks will be randomly selected until the final sample size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Imam Reza Hospital; Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714415333

Approval date

2023-11-21, 1402/08/30

Ethics committee reference number

IR.KUMS.MED.REC.1402.220

Health conditions studied

1

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

Mucosal lesions

Timepoint

weekly

Method of measurement

Using the Visual Analogue Scale questionnaire

2

Description

Lymphocytopenia

Timepoint

weekly

Method of measurement

Blood cell count test

3

Description

granulocytopenia

Timepoint

weekly

Method of measurement

Blood cell count test

4

Description

thrombocytopenia

Timepoint

weekly

Method of measurement

Blood cell count test

5

Description

anemia

Timepoint

weekly

Method of measurement

Blood cell count test

Secondary outcomes

empty

Intervention groups

1

Description

The control group does not receive any drug

Category

Prevention

2

Description

Intervention group: Famotidine tablets, 40 mg, daily, 4 hours and 3 hours before radiation therapy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Kermanshah Hospital

Full name of responsible person

Iman Fallah

Street address

Imam Reza Kermanshah Hospital; Parastar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Cirous Jalili

Street address

Shahid Beheshti Blvd

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Kermanshah

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cjalili@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Iman Fallah

Position

Radiation oncology resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Maliheh Dayani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Iman Fallah
Position
Radiation oncology resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Golestan 10; Golestan Street; Golha blvd
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Kermanshah
Province
Kermanshah
Postal code

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