

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The Investigating of Radiation Protection Effects of Metformin in Patients with Prostate Cancer Treated with Radiotherapy

Protocol summary

Study aim

The aim of this study is investigating of the effectiveness of metformin on radiation protection in patients with prostate cancer during treatment with radiotherapy.

Design

In this double-blind randomized controlled clinical trial with parallel group, sixty (60) patients will be allocated in one of two groups and received metformin or placebo, with blocked randomization method.

Settings and conduct

Patients referring to Department of Radiotherapy, Golestan Hospital, Ahvaz suffering from non-metastatic prostate cancer will be allocated in one of two groups based on blocked randomization. The intervention group receives metformin tablet at a dose of 1000 mg orally once a day and control group receive placebo orally once a day at day 0 (before starting radiation therapy) until one month after the final session of radiotherapy. Physicians and patients do not know if patients are receiving drug or placebo. The radiation protection effects will be measured by the level of antioxidant enzymes including superoxide dismutase, catalase, glutathione peroxidase and total antioxidant capacity in patients plasma in day 0, 14, 28, 42 and 56 during radiotherapy course and one month after the final session of radiotherapy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with localized prostate cancers that undergo definitive or postoperative external radiotherapy. Exclusion criteria: Metastasis; Renal or hepatic dysfunction; Cardiovascular failure; Severe respiratory disorders; Severe hematological disorders; Diabetic patients; Metformin allergy.

Intervention groups

The intervention group receive metformin tablet at a dose of 1000 mg orally once a day and control group receive placebo orally once a day.

Main outcome variables

The radiation protection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170307032933N3**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **prospective**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

Registration date

2018-10-22, 1397/07/30

Registrant information

Name

Pedram Nazari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Investigating of Radiation Protection Effects of Metformin in Patients with Prostate Cancer Treated with Radiotherapy

Public title

Radiation Protection Effects of Metformin in Prostate Cancer

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with localized prostate cancers that undergo definitive or postoperative external radiotherapy

Exclusion criteria:

Patients with metastatic prostate cancer Patients previously treated with radiotherapy or chemotherapy Patients with renal or liver dysfunction Patients with severe respiratory diseases (such as obstructive pulmonary disorders or severe asthma) Patients with hematological disorders (such as severe anemia or vitamin B12 deficiency) Diabetic patients Smoker patients Metformin hypersensitivity

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in two groups of test and control will be done by Block Balanced Randomization (BBR) method. The Randomization Sequence will be generated with using the free website at <http://www.randomization.com>.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The patients know they are participating in an investigation that is aimed to evaluate the metformin effect on prostate cancer but they are not informed that they receive placebo or metformin. The physician who evaluates the clinical status of patients and the nurse who prescribe the drug are not aware of the medication that patients receive. Medications are similar in appearance, color, smell and taste.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd

City

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Khouzestan

Postal code

15794-61357

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.AJUMS.REC.1397.451

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**

Radiation protection effect

Timepoint

At 0, every two weeks during radiotherapy course and one month after the final session of radiotherapy.

Method of measurement

Oxidative stress tests

Secondary outcomes**1****Description**

Urogenital complications

Timepoint

At 0, every two weeks during radiotherapy course and one month after the final session of radiotherapy.

Method of measurement

Toxicity Criteria of the Radiation Therapy Oncology Group

Intervention groups

1

Description

Intervention group: Metformin tablet at a dose of 1000 mg orally once a day will be prescribed before starting radiation therapy by one month after the final session of radiotherapy

Category

Prevention

2

Description

Control group: Placebo tablet at a dose of 1000 mg orally once a day will be prescribed before starting radiation therapy by one month after the final session of radiotherapy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Pedram Nazari

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Golestan Hospital, Golestan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Karandish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Sasan Razmjoo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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

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Full name of responsible person

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Latest degree

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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