Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The investigating of radioprotective effect of metformin against radiotherapy-induced urinary, gastrointestinal complications and genotoxicity in prostate cancer patients

Protocol summary

Study aim

The investigating of radioprotective effect of metformin against radiotherapy-induced urinary, gastrointestinal complications and genotoxicity in prostate cancer patients

Design

This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 60 patients with prostate cancer candidate for radiotherapy. Assignment of patients to the study groups will be done by random numbers generation and using computer by excel software.

Settings and conduct

This double-blinded study will be performed on 60 patients with prostate cancer candidate for radiotherapy in Golestan hospital, Ahvaz. The patients will be randomly assigned to one of two treatment groups of metformin or placebo. The patients and experimenters will not know about type of treatment and patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients localized prostate adenocarcinoma cancer, Prescribe of definitive or postoperative external beam radiotherapy, Consent to participate in the study; Exclusion criteria: Patients with metastatic prostate cancer, Previous history of radiation or chemotherapy, Renal and hepatic dysfunction, Patients with cardiovascular failure, Patients with severe respiratory problems, Patients with blood problems, Diabetic patients, Smoking patients.

Intervention groups

In first group, patients will receive oral metformin tablets (Chemi Darou Pharmaceutical Company, Iran) at a single dose of 1000 mg per day before the start of radiotherapy until one month after radiotherapy. Metformin tablets will be taken 2 hours before radiotherapy. In the second group, patients will receive a placebo with a similar dose of 1000 mg per day before the start of radiotherapy until one month after radiotherapy.

Main outcome variables

The Number of blood cells, Genotoxicity, Urinary and gastrointestinal complications

General information

Reason for update

The reason for this update is a mistake in registering the title of the trial. The ethics code which obtained and registered is related to this new title.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211213053377N1**
Registration date: **2022-01-20, 1400/10/30**
Registration timing: **prospective**

Last update: **2022-04-25, 1401/02/05**
Update count: **1**

Registration date

2022-01-20, 1400/10/30

Registrant information

Name

Sina Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3001 3374

Email address

larkhilv@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigating of radioprotective effect of metformin against radiotherapy-induced urinary, gastrointestinal complications and genotoxicity in prostate cancer patients

Public title

The radioprotective effect of metformin against radiotherapy-induced complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients localized prostate adenocarcinoma cancer Prescribe of definitive or postoperative external beam radiotherapy Consent to participate in the study

Exclusion criteria:

Patients with metastatic prostate cancer Previous history of radiation or chemotherapy Renal and hepatic dysfunction Patients with cardiovascular failure Patients with severe respiratory problems (such as obstructive pulmonary disease, severe asthma) Patients with blood problems (such as anemia, vitamin B12 deficiency) Diabetic patients Smoking patients

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random numbers generation and using computer by excel software. Random numbers will be generated in Excel with RAND function [(=RAND()*(60)] and with this function 60 random numbers will be created in the range of 1 to 60 in a column. Each patient will be assigned a two-digit code from 01 to 60. From the beginning of the first row, move down the column of random numbers and check the first two digits of the random numbers. The first 30 people seen in our code range will be placed in the first group (intervention) and the second 30 people will place in the second group (control). A person from hospital staff, who will not responsible for patient selection, enrollment, or treatment allocation, performs the randomization. The patients will be included in one of the two treatment groups before starting radiotherapy. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention (receiving oral metformin or placebo) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.

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

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2021-06-18, 1400/03/28

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.111

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
The Number of blood cells
Timepoint
Before first session of radiotherapy, once every two weeks during radiation therapy and one months after the end of radiotherapy
Method of measurement
Laboratory measurement of blood cell count

2

Description
Genotoxicity
Timepoint
Before first session of radiotherapy, once every two weeks during radiation therapy and one months after the end of radiotherapy
Method of measurement
Laboratory count of micronucleus in peripheral blood lymphocytes

3

Description
Urinary complications
Timepoint
Before first session of radiotherapy, once every two weeks during radiation therapy and one months after the end of radiotherapy
Method of measurement
Evaluation of acute urinary complications due to radiation therapy based on physician examination and patient symptoms

4

Description
Gastrointestinal complications
Timepoint
Before first session of radiotherapy, once every two weeks during radiation therapy and one months after the end of radiotherapy
Method of measurement
Evaluation of acute gastrointestinal complications due to radiation therapy based on physician examination and patient symptoms

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive oral metformin tablets (Chemi Darou Pharmaceutical Company, Iran) at a single dose of 1000 mg per day before the start of radiotherapy until one month after radiotherapy. Metformin tablets will be taken 2 hours before radiotherapy.
Category
Treatment - Drugs

2

Description
Control group: In the second group, patients will receive a placebo with a similar dose of 1000 mg per day before the start of radiotherapy until one month after radiotherapy. The appearance of a placebo is similar to that of metformin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Sina Hosseini
Street address
Golestan Hospital, Farvardin Ave., Golestan Blvd.
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6135733118
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Larkhilv@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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Email
badavim@yahoo.com
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
Sina Hosseini
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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Person responsible for updating data

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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