

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect celecoxib against radiotherapy induced acute toxicities in the patients with prostate cancer compared with placebo group.

Protocol summary

Summary

The purpose of this study was to assess the effect of celecoxib against radiation induced acute bowel and urinary toxicities in patients treated with radiotherapy for prostate cancer. All patients recently diagnosed with localized prostate cancer at the radiotherapy department of Mahdiyeh Center in Hamedan, Iran were evaluated for eligibility of participant in study. Referred Patients to local curative radiotherapy with external beam radiotherapy (EBRT) were invited to take part in the project. Forty prostate cancer patients undergoing external beam radiotherapy were enrolled to receive either placebo (n=20) or celecoxib(n=20). Inclusion and exclusion criteria included histologically confirmed prostate cancer, cases were candidates for definitive or postoperative external beam radiotherapy and have not radiographic evidence of distant metastasis. The patients received external beam radiotherapy up to 70 Gy at daily fractions of 1.8-2 Gy . The patients received oral celecoxib or placebo 200 mg twice daily. The first celecoxib or placebo administration 3 hr before each radiotherapy fraction and the second, 12 hr after than first consumption. RTOG based gastrointestinal (GI) and genitourinary (GU) acute toxicity scoring was performed pretreatment, at least once weekly during radiotherapy and once 1 month after the end of treatment. Before starting therapy, at 4 week of the therapy and 1 month after completion of the treatment blood samples were taken. The measurements contained complete blood count, coagulation parameters, creatinine level, serum urea, AP, AST, ALT and total bilirubine. Randomization was carried out by administrative personnel outside the trial in a double blind fashion. All participants and researcher were blinded to group assignment Random.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020626401N1**

Registration date: **2016-03-17, 1394/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-17, 1394/12/27

Registrant information

Name

Saeede Mirmohammadirad

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22718531

Email address

saeedemirmohamadirad@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-02-01, 1393/11/12

Expected recruitment end date

2016-02-16, 1394/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect celecoxib against radiotherapy induced acute toxicities in the patients with prostate cancer compared with placebo group.

Public title
Evaluation of the effect celecoxib against radiotherapy induced acute toxicities in the patients with prostate cancer compared with placebo group.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Histologically confirmed prostate cancer; normal levels of hemoglobin; leukocytes; platelets; creatinine; urea; bilirubine in the patients.
Exclusion criteria: clinical and radiographic evidence of distant metastasis before or during the trial; inability to receive celecoxib; simultaneous participation in another clinical trial; receive any other NSAIDs; patients with severe and uncontrolled cardiovascular; kidney; liver; inflammatory intestinal disease; coagulation disorders.

Age
No age limit

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Shahid Beheshti University of Medical Sciences

Street address

Faculty of paramedical Sciences, Qods Sq, Tehran

City

Tehran

Postal code

1971653313

Approval date

2015-03-01, 1393/12/10

Ethics committee reference number

SBMU.REC.1393.731

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

Urinary and bowel toxicities

Timepoint

weekly

Method of measurement

questionnaire

Secondary outcomes

1

Description

Blood factors

Timepoint

Start and ending in radiotherapy

Method of measurement

sampling

Intervention groups

1

Description

Intervention group: celecoxib; 200 mg; twice daily; in course of radiotherapy; 2 month.

Category

Treatment - Drugs

2

Description

Control group: placebo; 200 mg; twice daily; in course of radiotherapy; 2 month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Department of Mahdīyeh Center

Full name of responsible person

Ehsan Akbariamed

Street address

Radiotherapy Department of Mahdīyeh Center,
Parastar Avenue, Pajooheh Street, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Saeede Mir Mohammadirad

Street address

Faculty of Paramedical Sciences, Darband St. Qods
Sq, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Private

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeede Mirmohammadirad

Position

Masters

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty