

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the effects of quercetin ointment in the prevention of radiation-induced acute proctitis in prostate cancer patients

#### Protocol summary

##### Study aim

Use of quercetin ointment in the treatment of acute proctitis caused by radiotherapy in prostate cancer patients

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. For randomization after registration of eligible patients, they are assigned to treatment groups (Quercetin and placebo) based on a random algorithm following the dynamic allocation procedure.

##### Settings and conduct

The study to evaluate the effectiveness of quercetin ointment on the complication of acute proctitis caused by radiotherapy in prostate cancer patients undergoing treatment in Shahid Rajaei hospital in Babolsar and patients will be randomly divided into 2 groups. One group will be treated with placebo (as placebo) and the other group will be treated with Quercetin ointment, which are equalized in terms of color, shape, consistency and odor, and placebo and Quercetin ointment in the same and impossible dishes. In this study, patients and researchers were blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: prostate cancer patients undergoing radiotherapy with a field encompassing almost whole rectum Exclusion criteria: Patients with history of previous radiotherapy of pelvis region, Patients receiving treatment with anti-inflammatory drugs, Patients with acute or chronic pelvic infection

##### Intervention groups

Candidates will be randomly assigned to two groups. These patients receive either quercetin ointment (experimental group) or placebo (placebo group)

##### Main outcome variables

Radiotherapy induced proctitis based on the staging system of the Radiation Oncology Group (RTOG)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120707010205N10**

Registration date: **2022-09-19, 1401/06/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

##### Registration date

2022-09-19, 1401/06/28

##### Registrant information

##### Name

Dariush Moslemi

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1323 6752

##### Email address

d.moslemi@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-11-22, 1401/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effects of quercetin ointment in the prevention of radiation-induced acute proctitis in prostate cancer patients

## Public title

Evaluation of the effects of quercetin ointment in the prevention of radiation-induced acute proctitis in prostate cancer patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

prostate cancer patients undergoing radiotherapy with a field encompassing almost whole rectum and receive a minimum dose of 4000 cGy radiation

### Exclusion criteria:

Patients with history of previous radiotherapy of pelvis region Patients receiving treatment with anti-inflammatory drugs (NSAIDS, corticosteroids) Patients with inflammatory bowel disease (ulcerative colitis , Crohn's disease )

## Age

No age limit

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this method, packages containing medicine or placebo are placed in the box as a mixture, and when offered to the candidates, without looking inside the box, one of the packages is randomly selected and given to the candidate. The package containing the placebo is marked with the letter A and the package containing the medicine is marked with the letter B.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

For blinding, quercetin ointment and placebo are completely identical in terms of color, shape, consistency and smell, and are placed in the same containers so that the contents of the containers are not visible in terms of shape, color and consistency for the researcher and the patient. Somehow it is planned that neither the participant nor the researcher know which of the two control or test groups quercetin ointment or placebo is given.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical Sciences

##### Street address

Ganj afrooz street

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-47745

#### Approval date

2022-03-06, 1400/12/15

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.246

## Health conditions studied

### 1

#### Description of health condition studied

Radiation proctitis

#### ICD-10 code

K62.7

#### ICD-10 code description

Radiation proctitis

## Primary outcomes

### 1

#### Description

score of acute proctitis according to the staging system of the Radiation Oncology Group (RTOG)

#### Timepoint

At the beginning of the study and then every week after the start of quercetin ointment consumption

#### Method of measurement

RTOG criteria to evaluate acute proctitis reaction induced by radiation therapy

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: concurrent with beginning of radiotherapy, every day 5 cc of prepared quercetin ointment will be used by enema twice ingredients of

quercetin ointment: chitosan, quercetin  
2%, Carboxymethyl cellulose and sodium alginate  
substances will be from Sigma-Aldrich brand and will be  
combined in pharmacology laboratory, clean room of  
Babol University of Medical Sciences

#### Category

Treatment - Drugs

### 2

#### Description

Control group: concurrent with beginning of  
radiotherapy, every day 5 cc of prepared placebo ointment  
will be used by enema twice a day placebo ingredients:  
chitosan, Carboxymethyl cellulose, sodium alginate and  
edible food color (to make the combination look like  
quercetin ointment) substances will be from Sigma-  
Aldrich brand and will be combined in pharmacology  
laboratory, clean room of Babol University of Medical  
Sciences

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid rajaee hospital

##### Full name of responsible person

Dariush Moslemi

##### Street address

Shariati street

##### City

Babol

##### Province

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##### Postal code

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##### Phone

+98 11 3528 9259

##### Email

info@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr. Reza Ghadimi

##### Street address

Ganj afrooz street

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-47745

#### Phone

+98 11 9123 2959

#### Email

info@mubabol.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

##### Full name of responsible person

Dr Dariush Moslemi

##### Position

Lecturer/Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Radiotherapy

##### Street address

Department of Radiation Oncology, Babol University  
of Medical Sciences,

##### City

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr Dariush Moslemi

##### Position

Lecturer/Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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

Babol University of Medical Sciences

**Full name of responsible person**

Dariush Moslemi

**Position**

Assistant professor of radiation oncology

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Devison of radiation oncology, Babol University of Medical Sciences, ganj afrooz street, babol, mazandaran, iran

**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