

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The Evaluation of the Effect of Metformin on Pathologic Complete Response (pCR) to Chemoradiotherapy of Rectal Cancer in Non-Diabetic Patients

Protocol summary

Study aim

Determination of the Effect of Metformin on Pathologic Complete Response (pCR) to Chemoradiotherapy of Rectal Cancer in Non-diabetic Patients

Design

Two arm parallel group & single blinded randomized trial

Settings and conduct

This study will be conducted on patients with rectal cancer referred to radiation oncology department of Namazi hospital in Shiraz during September 2017 and April 2019. All patients will be done 2 cycles of chemotherapy (with XELOX regimen), long course RT (50.4 Gy in 1.8 - 2 Gy per fraction) followed by surgery. The case group will be taken metformin 500 mg Po Bid after eating and taking into account the contraindications (N = 45), and the control group will not be taken metformin (N = 45). The patient will be unaware of medication content (single blinded). Adverse effects of intervention will be evaluated. A standard surgical planning will be considered for all patients. Postsurgical pathology examination provides a description of the specimen.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 18 to 75 y/o with performance status <2 with rectal adenocarcinoma; non-diabetics treated from 2017 to 2019 with neoadjuvant chemoradiation followed by surgical resection at a single institution. Exclusion criteria: All patients treated with surgery or radiation alone; those with distant metastatic disease at the time of presentation; having another malignancy; a Hx of previous RT to pelvis; any contraindication for RT; and a Hx of hypersensitivity reaction to the medications.

Intervention groups

1- case group: taking metformin 500 mg Po Bid after eating and taking into account the contraindications (N = 45); 2- control group: not taking metformin (N = 45).

Main outcome variables

The primary outcome is pathologic complete response, and the secondary outcome includes side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190726044335N1**

Registration date: **2019-08-20, 1398/05/29**

Registration timing: **prospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Monireh Jelodari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4320

Email address

mjelodari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of the Effect of Metformin on Pathologic Complete Response (pCR) to Chemoradiotherapy of Rectal Cancer in Non-Diabetic Patients

Public title

Therapeutic effect of metformin in rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All non-diabetic patients with rectal adenocarcinoma aged 18 to 75 y/o and performance status <2

Exclusion criteria:

Treatment with surgery or radiation alone, distant metastasis, previous pelvic radiotherapy, and hypersensitivity reaction to the medications

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random numbers table

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient will not be unaware of the medication content

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Faculty of medicine, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71937-11351

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.SUMS.MED.REC.1398.104

Health conditions studied**1****Description of health condition studied**

Rectal cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes**1****Description**

Pathologic complete response

Timepoint

Post operation

Method of measurement

Pathologic examination

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

Side effects

Timepoint

Weekly during intervention course

Method of measurement

Radiation therapy oncology group toxicity criteria

Intervention groups**1****Description**

Intervention group: The patients with rectal cancer in the case group will be taken the metformin 500 mg Po Bid after eating and taking into account the contraindications.

Category

Treatment - Drugs

2**Description**

Control group: The patients with rectal cancer in the control group will not be taken the metformin.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Shapour Omidvari

Street addressThirty-Sixth room, Department of radiation oncology,
Namazi hospital, Namazi square**City**

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Web page address<http://www.sums.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street addressDeputy of Research, Shiraz University of Medical
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Web page address<http://research.sums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Monireh Jelodari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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oncology, Namazi hospital, Namazi square**City**

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Web page address<http://www.sums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shapour Omidvari

Position

Full Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Monireh Jelodari
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about main outcomes of the study

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centre

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of radiation oncology of Shiraz university of medical sciences

What processes are involved for a request to access data/document

Sending the request in writing or by email to the authors

Comments