

# 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 address**Thirty-Sixth room, Department of radiation oncology,  
Namazi hospital, Namazi square**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Phone**

+98 71 3647 4320

**Fax**

+98 71 3647 4320

**Email**

omidvari@sums.ac.ir

**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 address**Deputy of Research, Shiraz University of Medical  
Sciences, Zand Avenue**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Phone**

+98 71 3235 7282

**Fax**

+98 71 3212 2430

**Email**

vcrdep@sums.ac.ir

**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

**Street address**Forty-second room, Department of radiation  
oncology, Namazi hospital, Namazi square**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Phone**

+98 71 3647 4320

**Fax**

+98 71 3647 4320

**Email**

mjelodari@sums.ac.ir

**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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omidvari@sums.ac.ir  
**Web page address**  
<http://www.sums.ac.ir>

## Person responsible for updating data

### 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  
**Street address**  
Forty-second room, Department of radiation oncology, Namazi hospital, Namazi square  
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**Email**  
mjelodari@sums.ac.ir  
**Web page address**  
<http://www.sums.ac.ir>

## 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