

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial to compare the effectiveness of the total neoadjuvant therapy with standard approach in rectal adenocarcinoma patients

Protocol summary

Study aim

To compare the effectiveness of the total neoadjuvant therapy with standard approach in rectal adenocarcinoma patients

Design

This randomized and single-blind clinical trial with parallel and control groups will be conducted on 60 patients who will be randomly selected using the blocks.

Settings and conduct

Patients with rectal adenocarcinoma referring to Omid and Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with rectal adenocarcinoma based on pathological diagnosis; the zero to two level of Eastern Cooperative Oncology Group (ECOG); healthy functioning bone marrow; healthy functioning liver; healthy functioning kidneys. Exclusion criteria: Having simultaneous adenocarcinoma in other areas of the colon; having metastasis; history of previous malignancy; history of chemotherapy; history of pelvic radiotherapy; having inflammatory intestinal disease; having bilateral hip prosthesis; having allergic to 5-fluorouracil and its other derivatives; having allergic to oxaliplatin.

Intervention groups

In the intervention group, the patient will receive neoadjuvant treatment with pelvic radiotherapy along with capecitabine capsule, then neoadjuvant chemotherapy with FOLFOX or CapOx regimen, and finally definitive surgery. In the control group, the patient will undergo standard treatment in the form of first neoadjuvant treatment by pelvic radiotherapy with capecitabine capsules, then definitive surgery and finally adjuvant chemotherapy with FOLFOX or CapOx regimen.

Main outcome variables

Evaluation and comparison of the pathological complete

response, local recurrence and distant metastasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220723055527N1**

Registration date: **2022-11-07, 1401/08/16**

Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**

Update count: **1**

Registration date

2022-11-07, 1401/08/16

Registrant information

Name

Fereshteh Foroughi Pordanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 0626

Email address

foroughifrshte@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.
Scientific title	Blinding (investigator's opinion)
A clinical trial to compare the effectiveness of the total neoadjuvant therapy with standard approach in rectal adenocarcinoma patients	Single blinded
Public title	Blinding description
The effectiveness of the total neoadjuvant therapy in rectal adenocarcinoma patients	The data analyzer does not know which groups are located. The statistician will receive questionnaires as anonymously and in form A and B, and he/she does not know which are received the total neoadjuvant therapy or standard approach.
Purpose	Placebo
Treatment	Not used
Inclusion/Exclusion criteria	Assignment
Inclusion criteria:	Parallel
Patients with rectal adenocarcinoma based on pathological diagnosis The zero to two level of Eastern Cooperative Oncology Group (ECOG) Healthy functioning bone marrow Healthy functioning liver Healthy functioning kidneys	Other design features
Exclusion criteria:	
Having simultaneous adenocarcinoma in other areas of the colon Having metastasis History of previous malignancy History of chemotherapy History of pelvic radiotherapy Having inflammatory intestinal disease Having bilateral hip prosthesis Having allergic to 5-fluorouracil and its other derivatives Having allergic to oxaliplatin	Secondary Ids
Age	empty
No age limit	Ethics committees
Gender	
Both	1
Phase	Ethics committee
1-2	Name of ethics committee
Groups that have been masked	Ethics Committee of Mashhad University of Medical Sciences
• Outcome assessor	Street address
Sample size	Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
Target sample size: 60	City
Randomization (investigator's opinion)	Mashhad
Randomized	Province
Randomization description	Razavi Khorasan
In this study, we will use the restricted randomization method of block randomization base on statistical analysis system (SAS), computer software. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the	Postal code
	9195965919
	Approval date
	2022-04-19, 1401/01/30
	Ethics committee reference number
	IR.MUMS.MEDICAL.REC.1401.053
	2
	Ethics committee
	Name of ethics committee
	Research Ethics Committees of Sabzevar University of Medical Sciences
	Street address
	Nuclear Martyrs Boulevard, above the Memorial of the Unknown Martyrs, Campus of the University of Medical Sciences, Vice Chancellor for Research and Technology
	City
	Sabzevar
	Province
	Razavi Khorasan
	Postal code
	9617913114
	Approval date
	2023-12-12, 1402/09/21
	Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Rectal adenocarcinoma

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

The pathological complete response

Timepoint

One week after surgery

Method of measurement

Based on surgical pathology report

2

Description

Local recurrence

Timepoint

One year after intervention

Method of measurement

Pelvic computed tomography (CT) scan and colonoscopy

3

Description

Distant metastasis

Timepoint

One year after intervention

Method of measurement

Abdominal and pelvic CT scan

Secondary outcomes

1

Description

Complications of treatment

Timepoint

One, two and three weeks after treatment

Method of measurement

Based on the Common Terminology Criteria for Adverse Events (CTCAE)

Intervention groups

1

Description

Intervention group: The intervention group will first receive neoadjuvant treatment via pelvic radiotherapy

with capecitabine tablets, then neoadjuvant chemotherapy with FOLFOX or CapOx regimen, and finally definitive surgery.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive standard treatment in the form of neoadjuvant treatment via pelvic radiotherapy with capecitabine tablets, then definitive surgery and finally adjuvant chemotherapy with FOLFOX or CapOx regimen.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Fereshteh Foroughi Pordanjani

Street address

Omid Hospital, Al-Nandasht Square, Kooh Sangi Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9176613775

Phone

+98 51 3833 0626

Email

foroughifreshte@gmail.com

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Fereshteh Foroughi Pordanjani

Street address

Imam Reza Hospital, Imam Reza Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 1761 5063

Email

foroughifrshte@gmail.com

3

Recruitment center

Name of recruitment center

Vasei Educational and Medical Center

Full name of responsible person

Seyed Alireza Javadinia

Street address

Vasei hospital , Shohadaye Hasteii Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617747431

Phone

+98 51 4401 4000

Email

javadinia.alireza@gmail.com

Web page address

<https://medsab.ac.ir/index.aspx?pageid=339&p=1>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

Province

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9138813944

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Email

vcresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Kazem Hasanpour

Street address

Shohaday-e-hasteie boulevard

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

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Email

drhasanpour@yahoo.com

Grant name

A clinical Trial on the frequency of pathologic complete response in total neoadjuvant treatment in comparison with standard approach in patients with rectal adenocarcinoma

Grant code / Reference number

۴۰۲۰۴۹

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

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

50

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**

Mashhad University of Medical Sciences

Full name of responsible person

Fereshteh Foroughi Pordanjani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

Street address

Omid Hospital, Al-Nandasht Square, Kooh Sangi Street

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Mashhad

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Postal code
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fereshteh Foroughi Pordanjani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Fereshteh Foroughi Pordanjani
Position
Resident
Latest degree
Medical doctor
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Email
foroughifrshte@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In our study none of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Fereshteh Foroughi Pordanjani provides the data analysis to the applicants via email: foroughifrshte@gmail.com

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

Applicants can send emails to him and receive a response within a week.

Comments