

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the rate of complete clinical response following total neoadjuvant therapy by using chemoradiotherapy by Intensity modulated radiation therapy with simultaneous integrated boost (IMRT-SIB) in patients with lower rectal cancer; a Phase II randomized clinical trial

#### Protocol summary

##### Study aim

Investigation of complete clinical response in patients with lower rectal cancer treated with integrated chemoradiotherapy and boost technique

##### Design

This study is a single-arm phase 2 clinical trial, based on the 1-Sample 2-Sided Equality formula, about 29 patients are needed.

##### Settings and conduct

Data collection in this study will be through information registration forms specific to this project and follow-up in the form of telephone interviews and examination of the results recorded in the patients' files by colonoscopy, MRI and pathology modalities. The study period will be from 1402 to 1404 on patients referred to the Cancer Institute of Imam Khomeini Hospital

##### Participants/Inclusion and exclusion criteria

Entry requirements: age over 18 years with lower rectal cancer within 5 cm of the anal wedge and non-metastatic  
Conditions of non-entry: history of malignancy or digestive problems, inability to perform MRI, presence of active cancer in another part of the body

##### Intervention groups

Patients will undergo radiotherapy and chemotherapy simultaneously with capecitabine tablets five days a week. After radiotherapy, T3/4 or N+ patients undergo chemotherapy with one of XELOX or FOLFOX regimens. Evaluation of the response to treatment is done 12-16 weeks after the end of the treatment by MRI and colonoscopy. If there is a good response to the treatment, chemotherapy is continued until 16 weeks are completed and then a re-evaluation similar to the first evaluation is done. will be Patients with a complete clinical response will enter the Watch and Wait protocol if the patient agrees and other conditions are met (regular visit for follow-up and surgeon's approval).

##### Main outcome variables

The rate of tumor regression in MRI and colonoscopy/complete clinical response in patients/increasing the probability of not needing surgery in patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150929024266N6**

Registration date: **2024-02-24, 1402/12/05**

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

Last update: **2024-02-24, 1402/12/05**

Update count: **0**

##### Registration date

2024-02-24, 1402/12/05

##### Registrant information

##### Name

Reza Ghalehtaki

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2520

##### Email address

r-ghaletaki@student.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-06, 1402/10/16  
**Expected recruitment end date**  
2025-12-26, 1404/10/05  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluating the rate of complete clinical response following total neoadjuvant therapy by using chemoradiotherapy by Intensity modulated radiation therapy with simultaneous integrated boost (IMRT-SIB) in patients with lower rectal cancer; a Phase II randomized clinical trial

**Public title**  
Investigating the clinical response rate of patients with lower rectal cancer after combined treatment with intensity-modulated chemoradiotherapy and pre-surgical chemotherapy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Non-metastatic rectal cancer (>T2N0) that is less than 5 cm from the anal wedge  
**Exclusion criteria:**  
Inability to do MRI (whether mechanical or claustrophobia) Lack of proper MRI for disease staging Multiple comorbidities Inadequate blood, kidney, or liver indices for the possibility of receiving chemotherapy History of previous malignancies in the pelvis or other areas of the intestine, history of previous surgeries or radiotherapy in the pelvic area MSI-H patients who are candidates for immunotherapy History of IBD or FAP and other colon polyposis syndromes Active malignancies in other areas of the body.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Medicine-  
Tehran University of Medical Sciences

##### Street address

Poursina Street, Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2023-12-01, 1402/09/10

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.484

## 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

The rate of clinical response in MRI and colonoscopy

#### Timepoint

12 to 16 weeks after completion of treatment

#### Method of measurement

Reduction in size or complete disappearance of mass in  
MRI and colonoscopy

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The target population is people over 18 years of age with non-metastatic rectal cancer that are less than 5 cm from the anus and have good clinical conditions. Patients undergoing radiotherapy using 25-66/57 GTV, SIB and 25/45 CTV will receive five days a week (Saturday to

Wednesday) and will be treated with chemotherapy regimen with Xeloda 825 2m/mg twice a day orally between The first to fourteenth days will be arranged. SIB-PTV will be gross tumor on MRI plus 1 cm of geometric margin. After radiotherapy, T3/4 or N+ patients undergo chemotherapy with one of XELOX or FOLFOX regimens. Examining the results of patients 12-16 weeks after the end of treatment will be done by MRI and colonoscopy. The MRI report must be reviewed by two people separately or reported by an experienced person. If there is a good response to the treatment and the tumor has decreased in size significantly, the chemotherapy is continued until 16 weeks are completed, and then a re-evaluation similar to the first evaluation is done. Patients with complete clinical response enter the Wait and W protocol if the patient agrees and other conditions are met (regular follow-up visits and surgeon's approval). Complete response means the absence of residual activity in MRI and the absence of tumor, ulcer or polyp in colonoscopy. If there is no suitable response, the patient will be referred for surgery and the rest of the chemotherapy will be done after the operation.

**Category**

Treatment - Other

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

Imam Khomeini Hospital Complex, cancer institute

**Full name of responsible person**

Reza Ghaletaki

**Street address**

Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Cancer institute

**City**

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1419733141

**Phone**

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**Email**

isnr.group@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Akbari-Sari

**Street address**

No 206, First Floor, Official Building, Medical Faculty,

Poursina Street, 16th Azar Street, Keshavarz Blvd.

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1461884513

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research@tums.ac.ir

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

No

**Title of funding source**

Deputy of Research, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Reza Ghalehtaki

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Reza Ghalehtaki

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

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**Position**

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## **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