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-metastaticConditions 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
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2585

Fax
+98 21 6658 1604

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.

City
Tehran

Province
Tehran

Postal code
1461884513

Phone
+98 21 81631

Email
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

Street address
Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2520

Fax
+98 21 6119 2520

Email
r-ghaletaki@student.tums.ac.ir

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
Radiotherapy

Street address
Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2520

Fax
+98 21 6119 2520

Email
r-ghaletaki@student.tums.ac.ir

Person responsible for updating data

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
Radiotherapy

Street address
Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2520

Fax
+98 21 6119 2520

Email
r-ghaletaki@student.tums.ac.ir

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