

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Efficacy and Complications of Short Course versus Long Course Concurrent Chemo-radiotherapy followed by Consolidation Chemotherapy and Delayed Surgery among Patients with Rectal Cancer.

Protocol summary

Summary

Neoadjuvant radio-chemotherapy is a standard approach for patients with locally advanced rectal adenocarcinoma. We want to compare the complications, treatment tolerance and efficacy of short course concurrent chemoradiotherapy with the standard long-course regimen. In this double arm interventional non-blinded study patients with rectal adenocarcinoma located at 5 to 15 centimeters from anal verge without previous pelvic radiotherapy and chemotherapy will be enrolled. Individuals intolerant for chemotherapy, with existent other concomitant malignancy and distant metastasis will be excluded. Our estimated sample size is 72 people with attrition and lost to follow up taken account. The randomization is made by permuted blocks. The participant will undergo either short course radiotherapy consisted of 25 gray in 5 fractions in 5 days (one week) or long course radiotherapy consisted of 50 gray in 25 fractions (5 weeks) both with concurrent chemotherapy. Three to four weeks after completion of radiotherapy, participants receive one cycle of consolidation chemotherapy and then undergo total mesorectal excision surgery at least 8 weeks after last session of radiotherapy. The patients will be followed regularly for complications due to radiotherapy and chemotherapy before and after surgery to 30 days (for perioperative morbidity and mortality). Our primary outcome will be complications and treatment tolerance of these approaches compared together and secondary outcome would be pathologic response to neoadjuvant treatment, overall survival and local control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017110424266N3**

Registration date: **2017-11-12, 1396/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

Reza Ghalehtaki

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-15, 1397/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Complications of Short Course versus Long Course Concurrent Chemo-radiotherapy followed by

Consolidation Chemotherapy and Delayed Surgery among Patients with Rectal Cancer.

Public title

Short-Course Versus Long-Course Chemo-Radiotherapy in Cancer of Large Bowel

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Rectal Adenocarcinoma Confirmed by Pathology; Both Genders; Ages 18 to 80; Clinical Stages T3-4 or Lymph node Positive by MRI or Endosonography; Tumor Location 5 to 15 cm above anal verge; Good Performance Status (Eastern Cooperative Oncology Group 0-1). Exclusion Criteria: Concurrent Malignancy other than Rectal Cancer; No tolerance for Chemotherapy; Previous Pelvic Radiotherapy; Distant Metastasis; Impaired Renal Function.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Poursina Street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2017-09-16, 1396/06/25

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3475

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

Complications

Timepoint

At the Initiation of Radiotherapy up to one month after surgery

Method of measurement

Common terminology criteria for cancer related therapy adverse events

Secondary outcomes

1

Description

Postop Tumor Stage

Timepoint

After Surgery

Method of measurement

Pathology Report

Intervention groups

1

Description

1st Arm: Short course radiotherapy with 25 Gy in 5 fractions with concurrent chemotherapy regimen including Capecitabine 625mg/m2/bid for 5 days and Oxaliplatin 50mg/m2/day for 1 day then one cycle chemotherapy with XELOX regimen (Capecitabine 1000mg/m2/bid for 14 days and Oxaliplatin 130mg/m2/day for 1 day) 3 - 4 weeks after completion of radiotherapy then surgery at least 8 weeks after the radiotherapy last session.

Category

Treatment - Drugs

2

Description

2nd Arm (Control): Long course radiotherapy with 50 Gy in 25 fractions with concurrent Capecitabine 825mg/m2/bid for 5 days each week then one cycle chemotherapy with XELOX regimen (Capecitabine 1000mg/m2/bid for 14 days and Oxaliplatin 130mg/m2/day for 1 day) 3 - 4 weeks after completion of

radiotherapy then surgery at least 8 weeks after the radiotherapy last session.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute

Full name of responsible person

Mahdi Aghili

Street address

Department of Radiation Oncology, Cancer Institute,
Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tehran University of Medical
Sciences

Full name of responsible person

Shahin Akhondzadeh

Street address

No 206, First Floor, Official Building, Medical Faculty,
Poursina Street, 16th Azar Street, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tehran University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Radiation Oncology, Tehran University
of Medical Sciences

Full name of responsible person

Mahdi Aghili

Position

Head of Department of Radiation Oncology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty