

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and Complications of Short Course Radiotherapy with Concurrent Chemotherapy and Delayed Surgery among Patients with Rectal Cancer.

Protocol summary

Summary

Neoadjuvant radio-chemotherapy is a standard approach for patients with rectal adenocarcinoma. We want to test the possibility of adding chemotherapy to short course radiotherapy to enjoy the combined modalities benefits. In this single arm quasi experimental 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 30 people with attrition and lost to follow up taken account. The participant will undergo short course radiotherapy consisted of 25 gray in 5 fractions in 5 days with concurrent chemotherapy. Three weeks after completion of radiotherapy, participants receive one cycle of chemotherapy and then undergo total mesorectal excision surgery 8 week 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 feasibility of such approach and secondary outcome would be pathologic response to neoadjuvant treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121424266N2**

Registration date: **2016-12-25, 1395/10/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name

Reza Ghalehtaki

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-01, 1392/12/10

Expected recruitment end date

2015-03-02, 1393/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Complications of Short Course Radiotherapy with Concurrent Chemotherapy and Delayed Surgery among Patients with Rectal Cancer.

Public title

Role of Short-Term 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: **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

Tehran University of Medical Sciences Ethics Committee

Street address

Poursina Street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2014-02-15, 1392/11/26

Ethics committee reference number

9111188003-100785

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

Tumor Downstaging

Timepoint

After Surgery

Method of measurement

Pathology Report

2

Description

Node Downstaging

Timepoint

After Surgery

Method of measurement

Pathology Report

3

Description

Pathologic Response

Timepoint

After Surgery

Method of measurement

Based on Pathology Report

Intervention groups

1

Description

Short course radiotherapy with 25 Gy in 5 fractions with concurrent chemotherapy regimen including Capecitabine 850mg/m²/bid for 5 days and Oxaliplatin 85mg/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 weeks after completion of radiotherapy then surgery 8 weeks after the radiotherapy last session.

Category

Treatment - Other

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.

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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

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Position

Head of Department of Radiation Oncology

Other areas of specialty/work

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Resident

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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