Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

Comparison of the Clinical Response of Total nEoadjuvant Treatment of Two Methods of Long-term or Short-term cHemoRadiotherapy Followed by Consolidation Chemotherapy in Patients With Locally Advanced rectAl Cancer (TEHRAN) , a Randomized Controlled Clinical Trial

Protocol summary

Study aim
The purpose of this research is to compare two methods of TNT radiation therapy with same chemotherapy regimen.

Design
This study is a phase two tial, the sample size was estimated to be 114 based on similar trials, and then the patients were randomly divided into two groups.

Settings and conduct
Patients are treated with radiotherapy and chemotherapy at the Cancer Institution of Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria
Patients who are referred to the Cancer Institute between September 2023 and the end of March 2024, who has rectal adenocarcinoma from 5 cm to 15 cm from the anal verge and is Node positive or T3 and T4 based on MRI or EUS.In case of any other chemotherapy or radiotherapy treatment, will be disregarded in the trial.

Intervention groups
Group1: Long course radiotherapy with concurrent capecitabine(825mg/m2) Radiation is administered in conjunction with concomitant capecitabine (825mg/m2) group2: Short course radiotherapy with concurrent capecitabine(825mg/m2) Compared to conventional treatments, short-term radiotherapy has lower fraction numbers but higher radiation doses per fraction

Main outcome variables
Evaluation of complete clinical response rate after neoadjuvant treatment with MRI and colonoscopy

General information

Reason for update

Acronym
TEHRAN

IRCT registration information
IRCT registration number: **IRCT20230604058384N1**
Registration date: **2023-06-14, 1402/03/24**
Registration timing: **prospective**

Last update: **2023-06-14, 1402/03/24**
Update count: **0**

Registration date
2023-06-14, 1402/03/24

Registrant information

Name
Seyed Masoud Miratashi Yazdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Clinical Response of Total

nEoadjuvant Treatment of Two Methods of Long-term or Short-term cHemoRadiotherapy Followed by Consolidation Chemotherapy in Patients With Locally Advanced rectAl Cancer (TEHRAN) , a Randomized Controlled Clinical Trial

Public title
Comparison of the Clinical Response of Total Neoadjuvant Treatment of Two Methods of Long-term or Short-term Chemoradiotherapy in Rectal Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Locally advanced (T3-4, N+)adenocarcinoma of rectum is located 5 to 15 cm from anal verge is located 5 to 15 cm from anal verge
Exclusion criteria:
Familial syndromes e.g. lynch Previous history of cancer Previous history of chemotherapy Recurrent disease Metastatic disease Inability to perform MRI (Claustrophobia or prosthetic valve)
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: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization the permuted block randomization method was employed, in which blocks of four parts were formed, and the sequence where each part was assigned to each group was determined by random numbers. The randomization process was carried out using the web based application sealedenvelope.com.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
For the treatment of rectal cancer, there are primarily two radiation techniques. Long-term radiotherapy is 50.4 Gy delivered in 28 fractions, while short-term radiotherapy is 25 Gy delivered in 5 parts. These two approaches have not before been compared to one another, and the goal of the study is to accomplish just that.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
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Tehran
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Postal code
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Approval date
2022-11-15, 1401/08/24
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.238

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
complete clinical response
Timepoint
16 weeks from the start of treatment
Method of measurement
MRI, MR-TRG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Long-course radiation therapy with a dose of 50.4 Gy in 28 sessions along with concurrent chemotherapy with capecitabine at a dose of 825 mg/m2 and then consolidation chemotherapy with XELOX regimen for 6 cycles
Category
Treatment - Other

2

Description
Intervention group: Short-course radiation therapy with a dose of 25 Gy in 5 sessions along with concurrent chemotherapy with capecitabine at a dose of 825 mg/m2 and then consolidation chemotherapy with XELOX regimen for 6 cycles

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Cancer Institution

Full name of responsible person
Seyed Masoud Miratashi Yazdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
Tehran University of Medical Sciences

Proportion provided by this source
30

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
Seyed Masoud Miratashi Yazdi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
the risk that the original authors could not exploit the entire potential of the data they obtained, possible failures in patients' privacy protection, technical barriers such as the lack of standard formats, and possible data misinterpretation
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available