

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 trial, 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)

Phone

+98 21 8163 3626

Email address

masoudssu@yahoo.com

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 Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

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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Imam Khomeini Hospital Complex, Tohid Squire,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Fotouhi

Street address

6th floor of Research and Technology Vice-Chancellor,
Central Organization of Tehran University, Quds St.,
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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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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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