

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Comparison of pathologic response & safety in standard neoadjuvant therapy versus concomitant boost radiotherapy in patient with locally advanced rectal cancer referred to cancer institute from 2021 to 2024.

Protocol summary

Study aim

Assesment of pathologic response and adverse effect

Design

Controlled clinical trial with parallel, randomized, phase two groups on 100 patients, randomization with sealed envelope.

Settings and conduct

The first group:radiotherapy in two phases with a dose of 45 Gy to the pelvis and 4.5 Gy to GTV, and the involved nodes received chemotherapy at the same time as capitabine on radiotherapy days and underwent reevaluation and surgery after 12-10 weeks. Patients between chemoradiotherapy and surgery Patients undergo chemotherapy (2course ,every three weeks) with the xelox.Chemotherapy is continued with the Xelox after surgery(for six months)In the second group, the chemotherapy regimen is similar to the first group, and in radiotherapy, in addition to the dose of 4500 cGy per pelvis, the patient receives 1100 cGy dose of concomitant boost (220 cGy on the sixth day of each week).The boost dose is given to the GTV and the lymph nodes involved plus a margin of one to two centimeters.The study will be conducted at the Cancer Institute of Tehran.

Participants/Inclusion and exclusion criteria

KPS> 70; T3&4N0 and 12 cm from anal verge and T2N0 in 5 cm from AV and Node + without metastasis; metastasis; failure to receive a full chemotherapy and radiotherapy regimen; receiving chemotherapy before radiotherapy and recurrence

Intervention groups

The first group: radiotherapy in two phases with a dose of 45 Gy to the pelvis and 4.5 Gy to GTV, and the involved nodes .In the second group in radiotherapy, in addition to the dose of 4500 cGy per pelvis, the patient receives 220 cGy on the sixth day of each week. The boost is given to the GTV and the lymph node involved

plus a margin of one to two cm.

Main outcome variables

Pathological response, clinical response according to MRI and toxicity of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108052999N1**

Registration date: **2021-11-25, 1400/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

Registration date

2021-11-25, 1400/09/04

Registrant information

Name

Mehdi Aghili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2585

Email address

aghili@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of pathologic response & safety in standard neoadjuvant therapy versus concomitant boost radiotherapy in patient with locally advanced rectal cancer referred to cancer institute from 2021 to 2024.

Public title
Comparison of pathologic response & safety in standard neoadjuvant therapy versus concomitant boost radiotherapy in patient with locally advanced rectal cancer.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Good performance (kps> 70) T3,T4 N0 in 12 of anal verge Node+ T2N0 in 5 cm of anal verge No metastasis
Exclusion criteria:
Incomplete chemotherapy or radiotherapy Recurrence Chemotherapy before radiotherapy Metastasis

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, block randomization list created by sealed envelope website in two group with 4, 6, 8 block size

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
Imam Khomeini hospital Ethics Committee of research

Street address
Imam Khomeini hospital complex, Tehran University of Medical Science (ethics committee)

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2021-11-02, 1400/08/11

Ethics committee reference number
IR.TUMS.IKHC.REC.1400.235

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
Pathologic response

Timepoint
After surgery

Method of measurement
Tissue pathological assesment

2

Description
Treatment adverse effect

Timepoint
Weekly during treatment

Method of measurement
Examination, CBC and renal function test

Secondary outcomes

1

Description
Clinical response

Timepoint
Before intervention and before surgery

Method of measurement
MRI

Intervention groups

1

Description

Intervention group: In intervention group, the chemotherapy regimen is similar to the first group, and in radiotherapy, in addition to 4500 cGy per pelvis, the patient receives 1100 cGy dose of concomitant boost (220 cGy on the sixth sixth day of each week). The following complications are evaluated weekly according to the CTC-AE NCI VERSION 4.0 guideline: Rectitis Diarrhea Dermatitis Hematologic complications Post-op complications for one month after surgery including wound problems, abscesses, ostomy problems, ...

Category

Treatment - Other

2

Description

Control group: in this group standard treatment including two-phase radiotherapy with a dose of 4500 cGy to pelvis and 540 cGy dose of boost to GTV and nodes involved and concomitant chemotherapy with capecitabine at a dose of 825 mg / m² / bd on radiotherapy days and after 12-10 weeks. And surgery. Between chemoradiotherapy and surgery, patients undergoing chemotherapy (every three weeks) are on the following regimen: xelox (capecitabine 1000 mg / m², oxaliplatin 130 mg / m²). Reassessment is performed immediately before surgery by pelvic MRI. Chemotherapy is continued with the Xelox diet. The total duration of chemotherapy before and after surgery is six months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radition oncology ward in cancer institute/ imam khomeini hospital complex

Full name of responsible person

Mehdi Aghili

Street address

Imam khomeini hospital complex, Keshavarz Boulevard

City

Tehran

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Phone

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aghili@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

vice chancellor of research technology of Tehran University of Medical Ssciences, Ghods st., Keshavarz Boulevard,

City

Tehran

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1417653761

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+98 21 8163 3685

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vcr@tums.ac.ir

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

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

Mehdi Aghili

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Imam Khomeini hospital complexm, Keshavarz boulevard

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1419733141

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mehdi Aghili

Position

Associated professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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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

There is no plan for releasing...

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

No - There is not 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