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 localy advanced rectal cancer reffered 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 localy advanced rectal cancer reffered 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 localy 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 capcitabine at a dose of 825 mg / m^2 / 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 / m^2, oxaliplatin 130 mg / m^2). 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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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,

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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

Street address

Imam Khomeini hospital complexm, Keshavarz boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
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Person responsible for updating data

Contact

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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