Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The evaluation of pathologic complete response and clinical complete response in locally advanced rectal cancer who treated with total neoadjuvant therapy compared with standard treatment

Protocol summary

Study aim
Evaluation of pathologic and clinical response in locally advanced rectal cancer patients treated with Total Neoadjuvant Therapy compared to standard treatment

Design
Clinical trial with control group, with parallel, randomized, phase 2 groups on 70 patients which was calculated using non-inferiority formula.Sealedenvelope.com was used for randomization.Patients with locally advanced rectal cancer enter the study according to the inclusion criteria.

Settings and conduct
This study is designed at the radiation oncology ward, Cancer Institute, Imam Khomeini Hospital. In the TNT group, chemotherapy and radiotherapy are performed completely before surgery. In the standard protocol, radiotherapy is performed before surgery, and chemotherapy after. The studied variables will be recorded in the checklist at the beginning, during and after the end of treatment. Patients are followed for one month after surgery and then every three months to one year after treatment, and tests and imaging will be requested at the physician's discretion. Data will be analyzed using SPSS-version 16 software with T-test, non-parametric tests and quality tests.

Participants/Inclusion and exclusion criteria
Patients with advanced rectal cancer are included in the study. Patients who are not candidates for any of the treatments due to underlying renal, liver, or heart disease or who are unable to receive the full dose of the drug will not be included in the study.

Intervention groups
After randomization, for the intervention group, a treatment protocol called Total Neoadjuvant Therapy is considered and for the control group, a standard protocol is performed. In the intervention group, chemotherapy and radiotherapy are given completely before surgery. In the standard protocol, radiotherapy is performed before surgery, and chemotherapy after.

Main outcome variables
Clinical and pathological complete response

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200803048281N1**
Registration date: **2020-11-29, 1399/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-29, 1399/09/09**
Update count: **0**

Registration date
2020-11-29, 1399/09/09

Registrant information

Name
mahsa moshtaghian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6119 2585

Email address
mahsa.moshtaghian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of pathologic complete response and clinical complete response in locally advanced rectal cancer who treated with total neoadjuvant therapy compared with standard treatment

Public title

The effect of chemotherapy in rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with pathologically confirmed rectal cancer who are in locally advanced stage based on imaging

Exclusion criteria:

Patients diagnosed with Renal disease who are not candidates for chemotherapy or need to adjust the dose Patients diagnosed with hepatic disease who are not candidates for chemotherapy or need to adjust the dose Patients diagnosed with Cardiovascular disease who are not candidates for chemotherapy Patients with underlying colorectal disease such as Crohn's disease or ulcerative collitis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized to two groups by Permuted block method;The group treated with TNT approach and the group treated with standard treatment. Randomization method: block Randomization unit: individual Randomization tool: online software (Sealed Envelope Ltd. 2020) How to make a random sequence: Online software at: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 6 Nov 2020]

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

Ethics Committee in Research of Imam Khomeini Hospital Complex - Tehran University of Medical Scienc

Street address

Imam Khomeini Hospital Complex, Gharib St., Keshavarz Boulevard.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-09-04, 1398/06/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.160

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 Complete response to treatment

Timepoint

Before the surgery

Method of measurement

Based on preoperative history, examination and imaging

2

Description

Pathologic Complete response to treatment

Timepoint

After the surgery

Method of measurement

Based on the surgical pathology report

Secondary outcomes

1

Description
age
Timepoint
Before the intervention
Method of measurement
Asking the patient, patient ID card

2

Description
Sex
Timepoint
Before the intervention
Method of measurement
Patient ID card

3

Description
Performance
Timepoint
Before the intervention
Method of measurement
Based on Eastern Cooperative Oncology Group criteria

4

Description
Hematologic disorders
Timepoint
Before the intervention, weekly during chemotherapy and radiotherapy, and after treatment
Method of measurement
Complete blood count test

5

Description
Gastrointestinal side effects
Timepoint
Weekly during chemotherapy and radiotherapy
Method of measurement
Asking the patient, according to the Common Terminology Criteria for Adverse Events

6

Description
Neuropathic complications
Timepoint
Weekly during chemotherapy and radiotherapy
Method of measurement
Asking the patient, according to the Common Terminology Criteria for Adverse Events

7

Description
Staging of the disease
Timepoint
Before the intervention
Method of measurement
Based on endosonogeraphy or MRI

8

Description
Tumor distance from anal verge
Timepoint
Before the intervention
Method of measurement
Based on colonoscopy or endosonogeraphy or MRI

9

Description
Chemotherapy regimen
Timepoint
Before the chemotherapy
Method of measurement
Patient's file

10

Description
Radiotherapy technique
Timepoint
Before the radiation therapy
Method of measurement
Patient's file

11

Description
Radiotherapy dose
Timepoint
Before the treatment
Method of measurement
Patient's file

12

Description
Concurrent chemotherapy with radiotherapy
Timepoint
Before the treatment
Method of measurement
Patient's file

13

Description
Number of days between the last session of neoadjuvant treatment to surgery
Timepoint
Between the last session of neoadjuvant treatment to surgery
Method of measurement
Patient's file

14

Description
Number of days between the surgery to adjuvant treatment
Timepoint

Between the surgery to adjuvant treatment

Method of measurement

Patient's file

15

Description

Type of the surgery Low anterior resection or Abdominoperineal resection

Timepoint

After the surgery

Method of measurement

Patient's file

16

Description

Tumor margins in surgery

Timepoint

After the surgery

Method of measurement

Pathology report

17

Description

Response rate to treatment

Timepoint

After surgery

Method of measurement

Pathology report, based on Tumor regression grade

Intervention groups

1

Description

Intervention group: The intervention group will include patients who have all chemotherapy sessions before surgery, 3 sessions before radiotherapy and 3 sessions after radiotherapy. Medications include oxaliplatin 135 mg / m2, d1, and capecitabine (ACTe) 1000 mg / m2, d1-d14 every three weeks. Concurrently with radiotherapy, capcitabine 825 mg / m2 is prescribed during the radiotherapy treatment.

Category

Treatment - Other

2

Description

Control group: The control group includes patients who are treated by the standard protocol; preoperative chemoradiation and postoperative chemotherapy. Capecitabin is prescribed at a dose of 825 mg /m2 during radiotherapy, and after surgery, chemotherapy includes oxaliplatin 135 mg / m2, d1 and capecitabin (Acte company) 1000 mg / m2, d1-d14 every three weeks up to 5-6 courses.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiation oncology ward, Cancer institude, Imam khomeini Hospital Complex

Full name of responsible person

Mahsa Moshtaghian

Street address

Radiation Oncology ward, Cancer Institude, Imam Khomeini Hospital Complex, Gharib St.,Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2585

Email

mahsa.moshtaghian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Tehran university of medical sciences, Poursina St.,Qods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653911

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Web page address

https://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
Mahsa Moshtaghian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Cancer institute, Imam khomeini hospital complex, Qarib st, Keshavarz blvd
City
Tehran
Province
Tehran
Postal code
1419733147
Phone
+98 21 6119 2585
Email
mahsa.moshtaghian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Babaei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Cancer institute, Imam khomeini hospital complex, Qarib st, Keshavarz blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2585
Email
m-babaei@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahsa Moshtaghian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Cancer institute, Imam khomeini hospital complex, Qarib st, Keshavarz blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2585
Email
mahsa.moshtaghian@yahoo.com

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 more information.
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