Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the response and adverse effects of total neoadjuvant therapy (TNT) of advanced localized rectal cancer: a before-after clinical trial without control group

Protocol summary

Study aim

To assess the response and adverse effects of total neoadjuvant therapy (TNT) of advanced localized rectal cancer

Design

This is a before-after clinical trial without control group, in which eligible patients will be enrolled.

Settings and conduct

This study will be performed in the Imam Khomeini Clinic in Hamadan city on 25 eligible patients with advanced localized rectal cancer. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 75 years Advanced localized rectal cancer Normal liver, kidney and bone marrow condition Exclusion criteria: Previous chemotherapy Former pelvic radiotherapy Existence of distant metastasis

Intervention groups

Intervention group: Combination therapy of concomitant chemoradiotherapy includes: radiotherapy with 18 MV photon and total dose of radiotherapy 45 to 50.4 Gy in 25 to 28 sessions plus chemotherapy with 5FU injected at a dose of 1000 mg/m2 daily on the first to fifth days in the first week and the first to fifth days of the fifth week or 5FU orally at a dose of 825 mg/m2 every 12 hours on all days of radiotherapy. Four weeks after concomitant chemoradiotherapy, patients receiving chemotherapy with the FOLFOX regimen include the following drugs: Oxaliplatin at a dose of 85 mg/m2 on the first day of each course and 5FU at a dose of 600 mg/m2 on the first and second days of each course and Calcium Folinate at a dose of 200 mg /m2 on the first and second days of each course. Each course is 2 weeks apart and lasts up to 6 months.

Main outcome variables

Primary outcome: Complete pathological response, local recurrence, distant metastasis overall survival Secondary consequence: Hematologic and non-hematologic complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N431**
Registration date: **2022-06-19, 1401/03/29**
Registration timing: **prospective**

Last update: **2022-06-19, 1401/03/29**
Update count: **0**

Registration date

2022-06-19, 1401/03/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the response and adverse effects of total neoadjuvant therapy (TNT) of advanced localized rectal cancer: a before-after clinical trial without control group

Public title
Evaluation of the response and adverse effects of total neoadjuvant therapy (TNT) of advanced localized rectal cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 75 years Advanced localized rectal cancer Normal liver, kidney and bone marrow condition
Exclusion criteria:
Previous chemotherapy Former pelvic radiotherapy Existence of distant metastasis
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2021-12-12, 1400/09/21
Ethics committee reference number
IR.UMSHA.REC.1400.719

Health conditions studied

1

Description of health condition studied
Rectal cancer
ICD-10 code
C18.7
ICD-10 code description
Malignant neoplasm of sigmoid colon

Primary outcomes

1

Description
The rate of complete pathological response in surgery
Timepoint
6 to 8 weeks after the end of the intervention
Method of measurement
By pathological evaluation

2

Description
Local recurrence rate
Timepoint
Every 3 to 6 months up to 2 years after the end of the intervention
Method of measurement
By measuring tumor marker CEA and colonoscopy and pelvic CT scan

3

Description
Presence of distant metastasis
Timepoint
Every 3 to 6 months up to 2 years after the end of the intervention
Method of measurement
By CT scan of the chest and abdomen

4

Description
Overall survival rate
Timepoint
Up to 2 years after the end of the intervention
Method of measurement

By taking a history

Secondary outcomes

1

Description
Possible acute and chronic hematologic and non-hematologic complications
Timepoint
up to 2 years after the end of the intervention during patient follow-up
Method of measurement
By taking history, clinical examination and blood test

Intervention groups

1

Description
Intervention group: Combination therapy of concomitant chemoradiotherapy includes: radiotherapy with 18 MV photon and total dose of radiotherapy 45 to 50.4 Gy in 25 to 28 sessions plus chemotherapy with 5FU injected at a dose of 1000 mg/m2 daily on the first to fifth days in the first week and the first to fifth days of the fifth week or 5FU orally at a dose of 825 mg/m2 every 12 hours on all days of radiotherapy. Four weeks after concomitant chemoradiotherapy, patients receiving chemotherapy with the FOLFOX regimen include the following drugs: Oxaliplatin at a dose of 85 mg/m2 on the first day of each course and 5FU at a dose of 600 mg/m2 on the first and second days of each course and Calcium Folinate at a dose of 200 mg /m2 on the first and second days of each course. Each course is 2 weeks apart and lasts up to 6 months. Another chemotherapy regimen is XELOX, which include the following drugs: oral capsaicin 1000 mg/m2 every 12 hours for 2 weeks and then discontinued and repeated, plus an injection of oxaliplatin 130 mg/m2 on the first day of each course. Each course is 3 weeks apart and lasts up to 6 months. Patients will undergo surgery 6 to 8 weeks after the end of chemotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic in Hamadan city
Full name of responsible person
Mandana Biniaz
Street address
Imam Khomeini Clinic, Mirzadeh Eshghi Ave.
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6517838695
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Reza Shokoohi
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Mandana Biniaz
Position
Resident of Radio-Oncology
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address

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Person responsible for updating data

Contact

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Dr. Jalal Poorolajal

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Professor of Epidemiology

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Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be 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