

# 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> on the first day of each course and 5FU at a dose of 600 mg/m<sup>2</sup> on the first and second days of each course and Calcium Folate at a dose of 200 mg /m<sup>2</sup> 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> on the first day of each course and 5FU at a dose of 600 mg/m<sup>2</sup> on the first and second days of each course and Calcium Folate at a dose of 200 mg /m<sup>2</sup> 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/m<sup>2</sup> every 12 hours for 2 weeks and then discontinued and repeated, plus an injection of oxaliplatin 130 mg/m<sup>2</sup> 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 Biniiaz

##### Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

##### City

Hamadan

##### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3832 1371

#### Email

mandana.biniiaz.med@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Reza Shokoohi

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

#### 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 Biniiaz

##### Position

Resident of Radio-Oncology

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Radiotherapy

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Abdolazim Sedighi Pashaki

**Position**

Radio-Oncologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

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a.sedighipashaki@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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poorolajal@umsha.ac.ir

## 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