

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of treatment outcome of induction chemotherapy and then Neoadjuvant chemoradiotherapy and surgery in locally advanced rectal cancer

#### Protocol summary

##### Study aim

Evaluation of treatment outcome of induction chemotherapy and then Neoadjuvant chemoradiotherapy and surgery in locally advanced rectal cancer.

##### Design

first EUS or MRI abdomiopelvic and then pan CT is done. if no metastatic then induction chemotherapy with capox regimen every 3 weeks in 2 course then CHRT with capox and 4 weeks later restaging with CT scan and after 6-8 weeks after ChRt then patient goes to surgery .

##### Settings and conduct

thirty patient of newly diagnosis locally advanced rectal cancer refer to Imam Hossein Hospital is entered in study

##### Participants/Inclusion and exclusion criteria

1-adenocarcinoma maximum 15 cm from anal verge 2- TNM, T3,4 N+ 3- 2  $\geq$  performance status 4- (GFR  $\geq$  50) 5- liver function tests lower than upper limit normal 6- billirubin lower than 3rd upper limit normal 7- age upper than 18 years and lower than 65

##### Intervention groups

induction chemotherapy imen 2 courses then chemoradiation wuth capox then surgery was done

##### Main outcome variables

evaluation add pathologic complete response, R0 resection, sphincter preservation in lower rectum tumors, acute grade 3 hematologic, neurological, diarrhea toxicity or more during chemotherapy and chemoradiation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200420047139N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

##### Registration date

2020-06-02, 1399/03/13

##### Registrant information

###### Name

Behnaz Behzadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2221 4868

###### Email address

behnaz\_bzd@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

2018-05-22, 1397/03/01

##### Actual recruitment end date

2019-05-22, 1398/03/01

##### Trial completion date

2019-05-22, 1398/03/01

##### Scientific title

Evaluation of treatment outcome of induction chemotherapy and then Neoadjuvant chemoradiotherapy and surgery in locally advanced rectal cancer

##### Public title

Evaluation of treatment outcome of induction chemotherapy and then Neoadjuvant chemoradiotherapy and surgery in locally advanced rectal cancer

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

rectal cancer lower than 15 cm anal verge T3 or T4 or N+ 2 ≥ performance status GFR ≥ 50 liver function test upper limit normal bilirubin lower than 3rd upper limit normal more than 18 years , less than 65 years

### Exclusion criteria:

pathology except adenocarcinoma T1,2 ,N0 metastatic disease history of malignancy history of chemotherapy or radiation therapy pregnancy and breast feeding recurrent rectal cancer medical disease forbidden chemotherapy or radiation therapy

## Age

From **18 years** old to **65 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

Actual sample size reached: **29**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

not done before in Iranian

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University Of Medical Of Sciences  
Ethics Committee

##### Street address

Velenjak, Tehran Province

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2019-05-22, 1398/03/01

#### Ethics committee reference number

IR.SBMU.MSP.REC.1397.473

## Health conditions studied

### 1

#### Description of health condition studied

locally advanced rectal cancer

#### ICD-10 code

C20

#### ICD-10 code description

Malignant neoplasm of rectum

## Primary outcomes

### 1

#### Description

pathologic complete response

#### Timepoint

after surgery

#### Method of measurement

pathologic evaluation

## Secondary outcomes

### 1

#### Description

grade 3 or more of acute toxicity

#### Timepoint

during chemotherapy and chemoradiation

#### Method of measurement

observation symptoms and lab test

### 2

#### Description

R0 Resection

#### Timepoint

after surgery

#### Method of measurement

pathology

### 3

#### Description

sphincter preservation

#### Timepoint

after surgery

#### Method of measurement

type of surgery

## Intervention groups

### 1

#### Description

Intervention group: newly diagnosis locally advanced rectal cancer in included. they received induction chemotherapy with 2 course of CAPOX regimen every 3 weeks then ChRt with CAPOX and then surgery after 8 weeks. (capox regimen = capecitabine 1250 mg/m<sup>2</sup> po BD d1-14 and Oxaliplatin 50mg/m<sup>2</sup> iv weekly)

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Imam Hussein Hospital

**Full name of responsible person**

Ali Yaghoubi Joybari

**Street address**

Madani Street

**City**

Tehran

**Province**

Tehran

**Postal code**

12345678910

**Phone**

+98 21 7343 0211

**Email**

behnaz\_bzd@yahoo.com

**Web page address****Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Afshin zarghi

**Street address**Imam Hussein Hospital,Radiation Oncology  
Department**City**

Tehran

**Province**

Tehran

**Postal code**

12345678910

**Phone**

+98 21 2221 6594

**Email**

behnaz\_bzd@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Behnaz Behzadi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

Imam Hussein hospital,radiation oncology department

**City**

Tehran

**Province**

Tehran

**Postal code**

12345678910

**Phone**

+98 21 2221 6594

**Email**

behnaz\_bzd@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Evaluation of treatment outcome of induction chemotherapy and then Neoadjuvant chemoradiotherapy and surgery in locally advanced rectal cancer.

**When the data will become available and for how long**

base on programmer decision

**To whom data/document is available**

all physicians

**Under which criteria data/document could be used**

base on programmer decision

**From where data/document is obtainable**

sending email to programmer

**What processes are involved for a request to access data/document**

sending email and make decision

**Comments**