# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 iand 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 ≥ performance status 4- (GFR ≥ 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 thean 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 forrbidden 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 Ehics 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 pereservation
**Timepoint**
after surgery
**Method of measurement**
type of surgery

## Intervention groups

**1**

**Description**
Intervention group: newly diagnosis locally advanced rectal cancer in included.they recived Induction chemotherapy with 2 course of CAPOX regimen every 3 weeksthen ChRt with CAPOX and then surgery after 8 weeks.(capox regimen=capecitabine 1250 mg/m2 po BD d1-14and Oxaliplatin 50mg/m2 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**
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**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**
Behnaz Behzadi
**Position**
resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Radiotherapy
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## Person responsible for updating data

**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**

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**City**

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**Postal code**

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**Phone**

+98 21 2221 6594

**Email**

behnaz_bzd@yahoo.com

## 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**