

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Study of efficacy and safety of neoadjuvant chemotherapy with CAPOX regimen and neoadjuvant chemoradiation in complete pathologic response in locally advanced rectal cancer

Protocol summary

Summary

Purpose: The aim of this study is to evaluate the efficacy and safety of neoadjuvant chemotherapy in patients with clinical stage II-III resectable low rectal cancer. This study assumes that the addition of neoadjuvant chemotherapy to conventional neoadjuvant chemoradiation enhances the pathological response compared to historical controls treated with conventional neoadjuvant chemoradiation alone. Study design: This is a pilot single arm phase II clinical trial. Methods: Preliminary evaluations included comprehensive history and physical examination, colonoscopy, serum carcinoembryonic antigen (CEA) level, abdominal and pelvic ultrasonography and computed tomography (CT) scans and/or pelvic MRI and/or transrectal ultrasonography. Eligible patients must to have newly diagnosed locally advanced low rectal cancer, no prior therapy, ECOG performance status of 0 or 1, and normal organ function. Patients with prior history of chemotherapy or radiation therapy to the pelvis were excluded. Intervention: All patients will receive one course of chemotherapy with CAPOX regimen consisted of infusional Oxaliplatin 130 mg/m² first day and oral capecitabine, 2000 mg/m² twice daily during first to 14th days, after 3 weeks followed by chemoradiation (45 Gy) included conventional external beam radiotherapy using megavoltage linear accelerator photons. Concurrent chemotherapy consisted of oral capecitabine, 825 mg/m² twice daily during the whole period of the radiotherapy with weekend breaks (Tuesdays and Fridays). Then will receive 2 course of chemotherapy with CAPOX regimen with 3 weeks interwall. All patients will undergo standard surgery 6 weeks after completion of chemoradiation. Pathologic response will be defined through pathologic examination. Treatment-related complications will be determined according to the Common Terminology Criteria for Adverse Events (version 4.0). The endpoints of this study

include pathological complete response rate and adverse events

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082129403N2**

Registration date: **2016-09-24, 1395/07/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-24, 1395/07/03

Registrant information

Name

Mohammad Mohammadian Panah

Name of organization / entity

shiraz university of medical sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of efficacy and safety of neoadjuvant chemotherapy with CAPOX regimen and neoadjuvant chemoradiation in complete pathologic response in locally advanced rectal cancer

Public title
Effect of preoperative chemotherapy in the treatment of patients with locally advanced rectal cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: pathologically proved adenocarcinoma of the rectum; age 18 years old or older; clinically staged II-III tumor by MRI and/or EUS; ECOG performance status of 0 or 1; no previous history of malignancy, pelvic radiotherapy or chemotherapy; normal or adequate bone marrow reserve; normal or adequate liver and kidney function. Exclusion criteria: patients with distant metastatic disease; prior history of radiation therapy to the pelvis; prior history of chemotherapy for rectal cancer; active connective tissue disease such as scleroderma or Crohn's disease; uncontrolled diabetes mellitus, hypertension or recent cardiovascular disease; significant neuropathy; any previous or recent hypersensitivity or contraindication for chemotherapy agents.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Medical Research Ethics Committee of Shiraz school of Medical Sciences

Street address
Medical Research Ethics Committee of Shiraz school of Medical Sciences

City
Shiraz

Postal code

Approval date
2016-07-18, 1395/04/28

Ethics committee reference number
IR.SUMS.MED.REC.1395.23

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
pathological complete response

Timepoint
Before intervention and After surgical resection

Method of measurement
Pathologic examination

Secondary outcomes

1

Description
Treatment-related side effects

Timepoint
Weekly measurement from the first week to the end of intervention

Method of measurement
According to the Common Terminology Criteria for Adverse Events (version 4.0)

Intervention groups

1

Description
All patients will receive one course of chemotherapy with CAPOX regimen consisted of infusional Oxaliplatin 130 mg/m² first day and oral capecitabine, 2000 mg/m² twice daily during first to 14th days. after 3 weeks this treatment will be followed by chemoradiation included

conventional external beam radiotherapy using megavoltage linear accelerator photons. A total dose of 45 Gy external beam radiotherapy will be delivered via a daily fraction of 1.8 Gy, with five fractions per week. Concurrent chemotherapy consisted of oral capecitabine, 825 mg/m² twice daily during the whole period of the radiotherapy with weekend breaks (Tuesdays and Fridays). Then will receive 2 course of chemotherapy with CAPOX regimen with 3 weeks interwall. All patients will undergo standard surgery 6 weeks after completion of chemoradiation. Pathologic response will be defined through pathologic examination. Treatment-related complications will be determined according to the Common Terminology Criteria for Adverse Events (version 4.0). The endpoints of this study include pathological complete response rate and adverse events (gastrointestinal toxicity).

Category

Treatment - Other

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

Department of Radiation Oncology

Full name of responsible person

Mohammad Mohammadianpanah

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Department of Radiation Oncology, Namazi Hospital,

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Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Sayed Basir Hashemi

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Zand Street

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Shiraz

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty