Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of efficacy and safety of neoadjuvant chemotherapy with CAPOX regimen and neoadjuvant chemoradiation in complete pathologic responce 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
Iran (Islamic Republic of)
Phone
+98 71 9361 3511
Email address
mirzaies@sums.ac.ir

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 responce 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 scool 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

Street address

Department of Radiation Oncology, Namazi Hospital,

City

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

Street address

Zand Street

City

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

Mohammad Mohammadian Panah

Position

Professor of Radiation Oncology

Other areas of specialty/work

Street address

Namazi Hospital, Zand street

City

Shiraz

Postal code

Phone

+98 71 9361 3511

Fax

+98 71 9361 3511

Email

mirzaies@sums.ac.ir; sepidehmirzaie03@gmail.com; mohpanah@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Mdical Sciences

Full name of responsible person

Mohammad Mohammadian Panah

Position

Professor of radiation oncology

Other areas of specialty/work

Street address

Namazi hospital, Zand street

City

Shiraz

Postal code

Phone

+98 71 9361 3511

Fax

+98 71 9361 3511

Email

mirzaies@sums.ac.ir; sepidehmirzaie03@gmail.com; mohpanah@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mohammadian Panah

Position
Professor of Radiation Oncology
Other areas of specialty/work
Street address
Namazi Hospital, Zand street
City
Shiraz
Postal code
Phone
+98 71 9361 3511
Fax
+98 71 9361 3511
Email
mirzaies@sums.ac.ir; sepidehmirzaie03@gmail.com; mohpanah@gmail.com
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