

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The investigation of the efficacy and safety of preoperative short-course radiation therapy and chemotherapy followed by delayed surgery in patients with rectal cancer

Protocol summary

Study aim

To determine the efficacy and safety of preoperative short-course radiation therapy and chemotherapy followed by delayed surgery in patients with rectal cancer

Design

This study is a phase II single arm clinical trial. The sample size was determined equals 50 subjects. The eligible subjects will be consecutively selected among the patients with rectal cancer.

Settings and conduct

This study will be conducted on patients with rectal cancer referred to radiation oncology department of Namazi hospital in Shiraz in 2019. All patients will be done 3 cycles of chemotherapy (with CAPOX regimen), short course RT and surgery. For RT, a dose of 25 Gy in 5 fractions over 1 week will be prescribed. Adverse effects of RT will be scored. A standard surgical planning (low anterior resection or abdomino-perineal resection) will be considered for all patients. Postsurgical pathology examination provides a macroscopic description of the specimen.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with newly diagnosed rectal cancer with up to 16 cm distance from anal verge 2. Histologically confirmed adenocarcinoma; 3. Initial pathological stage of T3 or T4 and/or N+; 4. No history of initial distant metastases; 5. ECOG-performance status < 2 6. Age $\geq$ 18 years 7. Adequate bone marrow, hepatic and renal functions 8. Signing the informed consent
Exclusion criteria: 1. Pregnancy 2. Previous pelvic radiotherapy 3. Hypersensitivity to fluorouracil, oxaliplatin or capecitabine 3. Serious medical illness 4. Distance metastasis

Intervention groups

In this clinical trial, only one intervention group was designed in which patients with rectal cancer will receive

a cycle of chemotherapy (with CAPOX regimen) followed by short course RT followed by 2 weeks' rest followed by 2 cycles of chemotherapy followed by surgery.

Main outcome variables

Pathologic complete response; Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190119042415N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

AliAkbar Hafezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4320

Email address

hafezi_a@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of the efficacy and safety of preoperative short-course radiation therapy and chemotherapy followed by delayed surgery in patients with rectal cancer

Public title

Preoperative short-course radiation therapy in rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with newly diagnosed rectal cancer with up to 16 cm distance from anal verge Histologically confirmed adenocarcinoma Initial pathological stage of T3 or T4 and/or N+ No history of initial distant metastases ECOG-performance status < 2 6. Age ≥ 18 years Adequate bone marrow, hepatic and renal functions Signing the informed consent

Exclusion criteria:

Pregnancy Previous pelvic radiotherapy Hypersensitivity to fluorouracil, oxaliplatin or capecitabine Serious medical illness Distance metastasis

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Shiraz University of Medical Sciences

Street address

Faculty of medicine, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71937-11351

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.sums.med.rec.1397.437

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**

Pathologic complete response

Timepoint

Post operation

Method of measurement

Pathologic examination

Secondary outcomes**1****Description**

Side effects

Timepoint

Weekly during intervention course

Method of measurement

Radiation therapy oncology group toxicity criteria

Intervention groups**1****Description**

Intervention group: The patients with rectal cancer will receive a cycle of chemotherapy (with CAPOX regimen) followed by short course RT followed by 2 weeks' rest followed by 2 cycles of chemotherapy followed by surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Mohammad Mohammadianpanah

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Thirty-Sixth room, Department of radiation oncology,
Namazi hospital, Namazi square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Deputy of Research, Shiraz University of Medical
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Web page address

<http://research.sums.ac.ir>

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Akbar Hafezi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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Mohammad Mohammadianpanah

Position

Full Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Information about main outcomes of the study

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers in universities and scientific and research centers

Under which criteria data/document could be used

In order to improve the treatment of the disease and subsequent research and with the permission of the authors

From where data/document is obtainable

Department of radiation oncology of Shiraz university of medical sciences

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

Sending the request in writing or by email to the authors

Comments