Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of efficacy and safety of low-dose rate endorectal brachytherapy in patients with clinical stage T2N1 or T3-4N0-2 resectable low rectal cancer

Protocol summary

Summary

Purpose: The aim of this study is to evaluate the efficacy and safety of low-dose rate endorectal brachytherapy in patients with clinical stage II-III resectable low rectal cancer. This study assumes that the addition of low-dose endorectal brachytherapy 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 three fractions of 5 Gy endorectal brachytherapy, 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). 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: **IRCT201501059979N2**
Registration date: **2015-02-21, 1393/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-21, 1393/12/02

Registrant information

Name
Mohammad Mohammadianpanah
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Department of Radiation Oncology, Colorectal Research Center, Namazi Hospital, Shiraz University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-05-06, 1394/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy and safety of low-dose rate endorectal brachytherapy in patients with clinical stage T2N1 or T3-4N0-2 resectable low rectal cancer

Public title
Study of brachytherapy in rectal cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: • Pathologically proved adenocarcinoma of the rectum • Age 18 or older • Clinically staged II-III tumor by MRI and/or EUS • ECOG performance status of 0 or 1 • Tumors located at up to10 cm of the anus • 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 tumors >12 cm from the anal verge. • Near obstructing or bulky tumors which will not allow application of the endorectal applicator before or after chemoradiation • 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 **90 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
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 University of Medical Sciences
Street address
Medical Research Ethics Committee of Shiraz University of Medical Sciences
City
Shiraz
Postal code
71913613511
Approval date
2014-12-06, 1393/09/15
Ethics committee reference number
CT-P-9356-5686

Health conditions studied

1

Description of health condition studied
Rectal cancer
ICD-10 code
C20, C21.1
ICD-10 code description
Rectal and anal canal neoplasms

Primary outcomes

1

Description
pathological complete response
Timepoint
Before intervention and After surgical resection
Method of measurement
Pathologic examination

2

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)

Secondary outcomes

empty

Intervention groups

1

Description
All patients will receive three fractions of 5 Gy endorectal brachytherapy, each spaced apart by 4 days (+/- 1 day) and during 2 weeks. Subsequently, 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). 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 Mohammadianpanah

Position

Associate Professor of Radiation Oncology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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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