

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

To evaluate the safety and efficacy of simultaneous integrated boost in neoadjuvant short-course radiotherapy for rectal cancer A phase II clinical trial

Protocol summary

Study aim

Determine safety and efficacy of simultaneous integrated boost in neoadjuvant short-course RT for rectal cancer

Design

This is a phase 2, randomized, parallel-group, controlled clinical trial on 66 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this study CTV will be delineated, encompassing the GTV with appropriate margins. The mesorectum and regional lymph nodes will be included based on tumor location. All patients in this study will receive radiotherapy using IMRT technique. Short-course RT will be administered in 5 fractions, delivering 5 Gy per day to the gross tumor and regional lymph nodes (25 Gy over 5 consecutive days). A Simultaneous Integrated Boost will be applied, delivering an additional 5 Gy in 5 fractions (1 Gy per fraction) to the GTV, without increasing the total number of treatment sessions. Patients are treated in the Radio Oncology Department of Namazi Hospital, Shiraz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient with stage II and III rectal cancer and diagnosis confirmed by biopsy and tumor range is 15 cm from the anus and renal and liver and bone marrow with normal function, Exclusion criteria: distant metastasis at presentation and past history of radiation or surgery in pelvis for rectal cancer and comorbidity and patient's dissatisfaction for participating in trial

Intervention groups

Intervention group: Patients undergo short-term radiation therapy for 5 fractions, with 6 Gy administered in each session instead of 5 Gy, with an additional Gy given to the tumor mass. "Control group": Short-course radiation therapy: 5 fractions, 5 Gy given each day to the entire tumor and lymph nodes.

Main outcome variables

The incidence of adverse events: Pathological complete response ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250702066338N1**

Registration date: **2025-12-13, 1404/09/22**

Registration timing: **prospective**

Last update: **2025-12-13, 1404/09/22**

Update count: **0**

Registration date

2025-12-13, 1404/09/22

Registrant information

Name

saide Honarmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3843 6798

Email address

saideh1994.7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
To evaluate the safety and efficacy of simultaneous integrated boost in neoadjuvant short-course radiotherapy for rectal cancer A phase II clinical trial

Public title
To evaluate the safety and efficacy of simultaneous integrated boost in neoadjuvant short-course radiotherapy for rectal cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient with stage II and III rectal cancer Diagnosis confirmed by biopsy and pathology assessment Tumor range is 15 cm from anus ECOG= 0-2 Renal and liver and bone marrow with normal function
Exclusion criteria:
 Distant metastasis at presentation Past history of radiation or surgery in pelvis for rectal cancer The patient with comorbidity Patient's dissatisfaction to participate in the trial

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **33**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly selected from the hospital admission department with odd numbers in the admission office as the control group and even numbers in the admission office as the intervention group. They were numbered based on a random number table and named control and intervention groups using lowercase English letters.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

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
 Shiraz University of Medical Sciences, Zand street
City
 Shiraz
Province
 Fars
Postal code
 7184995495

Approval date
2025-06-23, 1404/04/02

Ethics committee reference number
IR.SUMS.MED.REC.1404.204

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 ratio

Timepoint
8 weeks after radiotherapy

Method of measurement
Biopsy and pathology assessment

Secondary outcomes

1

Description
Incidence of adverse events

Timepoint
Every week in radiotherapy course then every 3 months for 2 years

Method of measurement
History and physical examination

Intervention groups

1

Description
Intervention group: Short-course radiotherapy will be administered in 5 fractions, delivering 5 Gy per day to the gross tumor and regional lymph nodes (total dose: 25 Gy over 5 consecutive days). A Simultaneous

Integrated Boost (SIB) will be applied, delivering an additional 5 Gy in 5 fractions (1 Gy per fraction) to the GTV, without increasing the total number of treatment sessions.

Category

Treatment - Other

2

Description

"Control group": Short-term radiation therapy: 5 fractions, 5 Gy given each day to the entire tumor and lymph nodes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Mohammad mohamadianpanah

Street address

Namazi hospital, Molasadra St

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3612 5000

Email

mohpanah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

Street address

Shiraz University Of Medical Science, Zand street

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7134814336

Phone

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Email

mohammadi219@gmail.com

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

Mohammad mohamadianpanah

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mohammad mohamadianpanah

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mohammad mohamadianpanah
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Namazi hospital, Molasadra St
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable