Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 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

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Shiraz

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7193613311

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+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

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Shiraz Univercity Of Medical Science, Zand street

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7134814336

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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