

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Assessment of Efficacy for Neoadjuvant Chemotherapy with Modified FOLFOX6 compared to Chemoradiation for the Management of Locally Advanced Rectal Cancer: A Promising Therapeutic Approach

Protocol summary

Study aim

Investigation the effect of neoadjuvant chemotherapy on locally advanced rectal cancers including pathological complete response, 3-years disease free survival, down-staging of invasion, Down-staging if lymph nodes

Design

Two arm parallel group randomised trial for assessing effectiveness of chemotherapy in locally advanced rectal cancers. After initial steps, patients entered intervention or control groups as the odds numbers entered intervention group and even numbers entered control group.

Settings and conduct

patients with locally advanced rectal cancers from Hamadan province and its neighbors Kordestan and kermanshah, entered study. the main centers were Mahdiah radiotherapy and oncology center, Besat Hospital, Bu Ali Hospital, Razi lab,...

Participants/Inclusion and exclusion criteria

Inclusion: locally advanced rectal cancers, age between 18-75/No distant metastasis/proper blood condition/ Proper renal function/Proper liver function
Exclusion: recurrent rectal cancers/ previous pelvic radiation/ History of other malignancy After initial

Intervention groups

Adding neoadjuvant chemotherapy

Main outcome variables

Pathologic complete response, Down-staging of disease including decrease of invasion and lymph node involvement, 3-years disease free survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210308050628N1**

Registration date: **2023-12-08, 1402/09/17**

Registration timing: **retrospective**

Last update: **2023-12-08, 1402/09/17**

Update count: **0**

Registration date

2023-12-08, 1402/09/17

Registrant information

Name

Kamal Mohammadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3264 0020

Email address

km_282@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2019-11-30, 1398/09/09

Actual recruitment start date

2015-01-10, 1393/10/20

Actual recruitment end date

2019-12-30, 1398/10/09

Trial completion date

2023-06-28, 1402/04/07

Scientific title

The Assessment of Efficacy for Neoadjuvant Chemotherapy with Modified FOLFOX6 compared to Chemoradiation for the Management of Locally Advanced Rectal Cancer: A Promising Therapeutic Approach

Public title

Investigating the effect of neoadjuvant chemotherapy on locally advanced rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-75 Rectal cancer(Adenocarcinoma) confirmed by pathology locally advanced tumors No distant metastasis Proper Performance status(PS: 0-1) proper blood condition proper renal function proper liver function

Exclusion criteria:

Recurrent rectal cancer previous pelvic radiotherapy history of other malignancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Actual sample size reached: **286**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients referred to the Cancer center after essential and necessary task, entered the intervention and control group respectively. In other word, odds number entered intervention group and even numbers entered control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients had no role in selecting treatment type. Pathologists and Surgeons did not know the treatment type. The analysis team did not know the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Blv

City

Hamadan

Province

Hamadan

Postal code

65178

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.UMSHA.REC.1401.768

Health conditions studied

1

Description of health condition studied

Locally advanced Rectal cancers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pathological complete response, down-staging of tumor invasion and lymph nodes involvement, 3-years disease free survival

Timepoint

Before treatment, During treatment, after treatment and 3 years follow up

Method of measurement

Pathology, Clinic and Paraclinic

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: **بيهدل دڤخشيترشدف زائڤخفانفشعََ**

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Radiotherapy and Oncology Center

Full name of responsible person

Kamal Mohammadian

Street address

Parastar ST

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hamadan University of Medical Sciences

Proportion provided by this source

1

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Kamal Mohammadian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work

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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

No - There is not 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

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