# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 sdvanced 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 proviance and its neighbers Kordestan and kermanshah, entered stydy. the main centers were Mahdieh radiotjerapy and oncology center, besat Hospital,bu0ali Hospital, Razi lab,...

**Participants/Inclusion and exclusion criteria**
Inclusion: locally advanced rectal cancers, age between18-75/No distant metastasis/proper blood condition/ Proper renal fonction/Proper liver function
Exclusion: recurrent rectal cancers/ previous pelvic radiation/ History of other malignancyAfter initial

**Intervention groups**
Adding neoadjuvant chemotherapy

**Main outcome variables**
Pathologic complete response, Down-staging of didease including decreaseing of invasion and lymphnodes 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 comittee 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: ییهدل دثخشیتعرشدف زاثئخفاثقشحعَ
**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
**City**

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**Postal code**
6516934155
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+98 81 3838 0044
**Email**
km_282@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Kamal Mohammadian
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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**
Oncology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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