

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Neoadjuvant chemotherapy in locally advanced colon cancer: a randomized controlled trial

#### Protocol summary

##### Study aim

Evaluating the effect of neoadjuvant chemotherapy on histological response and tumour downstaging

##### Design

Randomised, parallel group, triple-blind, controlled multi center trial

##### Settings and conduct

This clinical trial will be conducted at Imam Reza Hospital and Ghaem hospital in Mashhad. Surgeon, pathologist and radiologist and assessor of quality of life, as well as data analyst, will be blinded to the assigned groups.

##### Participants/Inclusion and exclusion criteria

Non-metastatic colon cancer (Adenocarcinoma) in stage T3 with the involvement of local lymph nodes or T4 with or without the involvement of local lymph node, uncomplicated primary tumour requiring surgery (obstruction, perforation, bleeding), age between 18 and 75 years and ECOG functional status between 0-1

##### Intervention groups

Performing 6-week chemotherapy with mFOLFOX 6 or CapeOx and then carry out surgery and continue chemotherapy for 18 weeks.

##### Main outcome variables

Disease Free Survival and histological response after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130819014404N2**

Registration date: **2018-12-12, 1397/09/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

##### Registration date

2018-12-12, 1397/09/21

##### Registrant information

###### Name

Majid Khadem-Rezaiyan

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 9262

###### Email address

khademrm831@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-30, 1397/09/09

##### Expected recruitment end date

2019-05-30, 1398/03/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Neoadjuvant chemotherapy in locally advanced colon cancer: a randomized controlled trial

##### Public title

Chemotherapy in locally advanced colon cancer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Adnocarcinoma Stage T3 with lymph node involvement and T4 Non metastatic Primary tumor without complications which needs surgery (i.e. obstruction, perforation, bleeding) Age between 18-75 Functional

status ECOG between 0-1

**Exclusion criteria:**

Contraindication for receiving contrast for imaging Major surgery in less than 28 days prior to recruiting to the study Co-existence of other cancers Past medical history of other cancers

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **58**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization on individuals was performed using a table of random numbers. Allocation concealment was carried out.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The surgeon, pathologist and radiologist are unaware of allocated groups. Besides, the outcome assessor who evaluates the quality of life is unaware of the allocated groups. The data analyser will be blinded to the intervention groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Medical Faculty of Mashhad University of Medical Sciences

**Street address**

Medical Faculty, University Campus, Azadi Sq.,

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Approval date**

2018-07-25, 1397/05/03

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1397.408

**Health conditions studied**

1

**Description of health condition studied**

Cancer of the large intestine

**ICD-10 code**

C18

**ICD-10 code description**

Malignant neoplasm of colon

**Primary outcomes**

1

**Description**

Histological response and down staging of tumor

**Timepoint**

After surgery

**Method of measurement**

Pathological and radiological examination

2

**Description**

Disease Free Survival

**Timepoint**

One year after intervention

**Method of measurement**

No relapse of cancer

**Secondary outcomes**

1

**Description**

Overall survival

**Timepoint**

1 year after surgery

**Method of measurement**

The patient is alive

2

**Description**

The safety and tolerably of chemotherapy before surgery

**Timepoint**

60-day mortality after surgery

**Method of measurement**

The patient is alive

3

**Description**

Quality of life

**Timepoint**

At baseline, 6 months and one year after the completion of the study

## Method of measurement

Questionnaires EORTC QLQ-CR29 and EORTC QLQ-C30

## Intervention groups

### 1

#### Description

Intervention group: performing 6 week chemotherapy with mFOLFOX 6 or CapeOx and then carry out surgery and continue chemotherapy for 18 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Initial surgery followed by chemotherapy with mFOLFOX 6 or CapeOx for 24 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza (p) Hospital

##### Full name of responsible person

Dr. Alireza Baari

##### Street address

Imam Reza (p) Hospital, Imam Reza Sq., Ibn Sina Ave.,

##### City

Mashhad

##### Province

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##### Postal code

91379-13316

##### Phone

+98 51 3854 3031

##### Email

dr.alireza.baari@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Qaem Hospital

##### Full name of responsible person

Dr. Alireza Baari

##### Street address

Qaem Hospital, Ahmadabad Ave., Shariati Sq.,

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##### Phone

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## Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Tafaghodi

##### Street address

Ghoreishi Building, Before Golestan Crossroad, Daneshgah Ave., Mashhad, Iran

##### City

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##### Province

Razavi Khorasan

##### Postal code

91388-13944

##### Phone

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##### Email

Ramresearch@mums.ac.ir

#### Grant name

Dr. Alireza Baari

#### Grant code / Reference number

mums-۹۶۱۲۲۸

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohamad Moeini

##### Position

Fellow of hematology and oncology

##### Latest degree

Specialist

##### Other areas of specialty/work

Hematology

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Imam Reza Hospital, Imam Reza Sq., Ibn Sina Ave.,

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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moeininm901@mums.ac.ir

## 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

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