Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Ghoreishi Building, Before Golestan Crossroad, Daneshgah Ave., Mashhad, Iran
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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
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Specialist
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Hematology
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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
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