Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Xelox with Folfox Chemotherapy in Patients with Non-Metastatic Colon Cancer

Protocol summary

Study aim
Comparison of Xelox Chemotherapy with Folfox in Patients with Non-Metastatic Colon Cancer

Design
Clinical trial with control group, with parallel, non-blinding, randomized, phase 2 groups on 48 patients. Excel software rand function was used for randomization.

Settings and conduct
Forty-eight patients with stage II colorectal cancer are randomly assigned to two groups using randomized block after enrollment. The studied diets are Xelox and Folfox. The study site is the blood clinic of Qazvin province hospital. Metastases are examined.

Participants/Inclusion and exclusion criteria
48 patients in stage II colorectal cancer Inclusion criteria: - Age 18 years - One or two of the following tests performed up to 30 days before the start of the study: • Platelets ≥ 100000 White blood cells WBC ≥ 3000 - Hemoglobin ≥ 10 Total bilirubin ≤ 1.5 times the maximum normal • Serum creatinine ≤ 1.5 times the maximum normal level Exclusion criteria: - Pregnancy, breastfeeding - According to the treating physician (due to safety or inability of the patient to cooperate) causes the patient to be unable to participate in the study - Inability to swallow

Intervention groups
Group A: XELOX includes a 2-hour intravascular injection. Oxaliplatin injection of 130 mg / m2 on day 1 plus oral capsaicin 1000 mg / m2 twice daily on days 15-1 of the 3-week cycle on an outpatient basis. The first dose of capsaicin is given on the evening of day 1 and the last dose on the morning of day 15 (28 doses per cycle). Group B: FOLFOX includes weekly injections of 5FU 500 mg / m2, Leucovorin 500 mg / m2 for 6 weeks and oxaliplatin 85 mg / m2 in weeks 1, 3, 5, repeated for 3 periods.

Main outcome variables
Comparison of local recurrence and distant metastasis of patients in the two groups after treatment and evaluation of patient survival in the two groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210913052454N1**
Registration date: **2022-04-28, 1401/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-28, 1401/02/08**
Update count: **0**

Registration date
2022-04-28, 1401/02/08

Registrant information

Name
Alireza Esmaeilzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3379 0620

Email address
dr.nafas.rastgoo.20@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of Xelox with Folfox Chemotherapy in Patients with Non-Metastatic Colon Cancer

Public title
Comparison of Xelox with Folfox Chemotherapy in Patients with Non-Metastatic Colon Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Platelet ≥ 100000 White blood cell WBC ≥ 3000 - hemoglobin ≥ 10 Serum creatinine ≤ 1.5 times the maximum normal level
Exclusion criteria:
Pregnancy, breastfeeding Inability to swallow
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into two groups a and b using the balance block randomization method. The size of each block is 4. The method of balanced randomization allocation for participants in a randomized clinical trial study is the effect of Xelox (group a) and Folfox (group b) chemotherapy on reducing local recurrence and distant metastasis of non-metastatic colon cancer patients. The tool is random allocation software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Vellayat hospital, Tavon Sq, Sayyad Blvd (Bist-o Do Bahman Blvd), Qazvin, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
76161347193
Approval date
2021-08-03, 1400/05/12
Ethics committee reference number
IR.QUMS.REC.1400.202

Health conditions studied

1

Description of health condition studied
colorectal cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

Primary outcomes

1

Description
Local recurrence
Timepoint
One year period
Method of measurement
Colonoscopy

2

Description
Distant metastasis
Timepoint
One year period
Method of measurement
Tumor marker and CT scan

Secondary outcomes

1

Description
Patient survival
Timepoint
2 years
Method of measurement
Follow up patients

Intervention groups

1

Description
Intervention group:Xelox diet group.Includes a 2-hour intravascular injection. Oxaliplatin injection of 130 mg /

m2 on day 1 plus oral capsaicin 1000 mg / m2 twice daily on days 15-1 of the 3-week cycle on an outpatient basis. The first dose of capsaicin is given in the evening of day 1 and the last dose in the morning on day 15 (28 doses per cycle).

Category

Treatment - Drugs

2

Description

Control group:Folfox diet group.Includes weekly injections of 5 FU 500 mg / m2, Leucovorin 500 mg / m2 for 6 weeks and oxaliplatin 85 mg / m2 at weeks 1, 3, 5, repeated for 3 periods.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vellayat hospital

Full name of responsible person

Alireza Esmaeilzadeh

Street address

Vellayat hospital, Tavon Sq, Sayyad Blvd (Bist-o Do Bahman Blvd), Qazvin, Qazvin, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Research Branch of Qazvin University of Medical Sciences

Street address

Vellayat hospital, Tavon Sq, Sayyad Blvd (Bist-o Do Bahman Blvd), Qazvin, Qazvin, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Alireza Esmaeilzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after individuals are unidentified

When the data will become available and for how long

After published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any analysis of the submitted data is allowed. A message should be sent to the author's email in order to access the data or documents.

From where data/document is obtainable

Refer to the email of Dr. Alireza Esmailzadeh

What processes are involved for a request to access data/document

After the publication of the article, the applicant is able to access the information by sending an email to the author and its duration is about one month.

Comments