

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of oral nano-formulation of Curcumin efficacy, as an adjuvant to Capecitabine [Xeloda] + Oxaliplatin (XELOX) or Folinic Acid + 5-Flurouracil + Oxaliplatin (FOLFOX) regimen treatment for metastatic colorectal cancer: A triple blinded, randomized clinical trial

Protocol summary

Study aim

Evaluation of oral nano-formulation of Curcumin efficacy, as an adjuvant to Capecitabine [Xeloda] + Oxaliplatin (XELOX) or Folinic acid + 5-Flurouracil + Oxaliplatin (FOLFOX) regimen treatment for metastatic colorectal cancer

Design

A Phase 2 Triple-blind Parallel Randomized Clinical trial with control group on 60 patients. Randomization.com was used for randomization.

Settings and conduct

Patients referred to the hematology oncology and radiotherapy oncology department of Imam Reza Hospital, Qaem or Omid of Mashhad, with obtained informed consent form.

Participants/Inclusion and exclusion criteria

Metastatic colorectal cancer without NRAS and KRAS mutation or not indicated for targeted therapy; Under XELOX or FOLFOX regime treatment; Patient consent to enter the study; Eastern cooperative oncology group (ECOG) 0/1; Neutrophil count $\geq 1.5 \times 10^3/\mu\text{L}$; Platelet count $\geq 10 \times 10^4/\mu\text{L}$, hemoglobin $\geq 9\text{g/dL}$; Creatinine $\leq 1.5\text{ mg/dl}$; ALT, AST $\leq 5 \times \text{ULN}$; total bilirubin $\leq 2 \times \text{ULN}$

Intervention groups

nanocurcumin 40 mg formulated by Exiranano Sina Inc. thrice a day after meal during sixtet 21-day courses (XELOX or FOLFOX) in intervention group. Control group: placebo contain all the ingredients of the main capsule and only curcumin-free with the same appearance in the control group one capsule thrice a day after each meal during sixtet 21-day course (Xeloda or FOLFOX) formulated by ExirNanoSina Inc.

Main outcome variables

Periodic radiographic checks for metastatic extent C-Reactive Protein(CRP)- Carcinoembryonic Antigen(CEA)- Carbohydrate Antigen 19-9 (CA19-9) The Response

Evaluation Criteria in Solid Tumours (RECIST1.1)[Radiographic response of the tumor]

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N7**
Registration date: **2021-03-13, 1399/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-13, 1399/12/23**

Update count: **0**

Registration date

2021-03-13, 1399/12/23

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

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
Evaluation of oral nano-formulation of Curcumin efficacy, as an adjuvant to Capecitabine [Xeloda] + Oxaliplatin (XELOX) or Folinic Acid + 5-Flurouracil + Oxaliplatin (FOLFOX) regimen treatment for metastatic colorectal cancer: A triple blinded, randomized clinical trial

Public title
Evaluation of oral nano-formulation of Curcumin efficacy, as an adjuvant to XELOX or FOLFOX regimen treatment for metastatic colorectal cancer: A triple blinded, randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with confirmed histological or cytological diagnosis of metastatic colorectal cancer (stage 4) Based on ultrasound results without NRAS and KRAS mutation or no candidate for target therapy(Contraindications or economic incapability) XELOX or FOLFOX regimen candidate Patient consent to study Eastern cooperative oncology group (ECOG) 0/ 1 Hemoglobin \geq 9g/dL, Neutrophil count \geq 1.5 \times 10³/ μ L, Platelet count \geq 10 \times 10⁴/ μ L Creatinine \leq 1.5 mg/dl, ALT,AST \leq 5 \times ULN, total bilirubin \leq 2 \times ULN

Exclusion criteria:

current antioxidant users pregnancy or lactation history of hypersensitivity to formulation components diagnosed with more than one cancer history of HF history of autoimmune or immunodeficiency (medical or drug induced) other than chemotherapy history of HBV or HCV candidate of curative surgery

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using Randomization.com will implemented. This method uses simple randomization models such as head or tail, using a random number table or using computer randomization methods, and for

example, each client by dropping coin will include in control or intervention group. This method is very simple to implement. Patients will receive enrollment number 1 or 2, respectively, and enter one of two groups of drugs or placebo.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Nano-curcumin and placebo soft gels packages in identical bottle will be delivered to the clinician. Patients who meet the inclusion criteria will be selected by clinician to be included in the study, randomly assigned to a drug or placebo group and be given a bottle with A or B mark. The physician and the resident of clinical pharmacy will evaluate patients in the course of treatment. Data collection and analysis will be performed by the clinical pharmacy resident and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences,

Street address

Mashhad University of Medical Sciences,Vakil Abad Blvd

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Province

Razavi Khorasan

Postal code

9415945344

Approval date

2020-12-28, 1399/10/08

Ethics committee reference number

IR.MUMS.REC.1399.538

Health conditions studied

1

Description of health condition studied

Metastatic colorectal cancer

ICD-10 code

C78.5

ICD-10 code description

Secondary malignant neoplasm of large intestine and rectum

Primary outcomes

1

Description

Metastatic extent

Timepoint

after three courses of chemotherapy and the end of six courses

Method of measurement

Periodic Radiography

2

Description

Assess CRP levels

Timepoint

At the beginning and after the end of three and six chemotherapy courses

Method of measurement

Blood test

3

Description

Assess CEA and CA19-9 levels

Timepoint

At the end of three courses and six courses of chemotherapy

Method of measurement

Blood test

4

Description

Radiographic response of the tumor

Timepoint

after three courses of chemotherapy and the end of six courses

Method of measurement

(RECIST1.1), based on the doctor's clinical examination

Secondary outcomes

1

Description

Evaluate patient performance

Timepoint

At the end of three and six chemotherapy courses

Method of measurement

EORTC QLQ-C30 questionnaire and based on the doctor's clinical examination

2

Description

Incidence of chemotherapy side effects including neuropathy, HFS; based on the doctor's clinical examination.

Timepoint

At the beginning and end of six courses

Method of measurement

CTCAE v5 criteria and based on the doctor's clinical examination.

3

Description

Liver function test

Timepoint

At the beginning and end of six courses

Method of measurement

CTCAE v5 criteria and based on the clinician's clinical examination and sonography

Intervention groups

1

Description

Intervention group: Nanocurcumin 40 mg capsule formulated by Exir Nanosina Inc. thrice a day (after breakfast, lunch and dinner) for 6 21-day courses of XELOX or FOLFOX regimen

Category

Treatment - Drugs

2

Description

Control group: Placebo with the same appearance prepared by Exir nano Sina Inc. thrice a day (after breakfast, lunch and dinner) for 6 21-day courses of XELOX or FOLFOX regimen

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Abolghasem Allahyari

Street address

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2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Sare Hosseini

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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

3**Recruitment center****Name of recruitment center**

Qaem Hospital

Full name of responsible person

Hossein Rahimi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Faculty of Pharmacy, Ferdowsi University, Vakilabad boulevard

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Jannati Yazdan Abad

Position

Clinical Pharmacy Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Medical doctor

Other areas of specialty/work

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The findings will be published in an article. Study protocol and statistical analysis will be used for article publication. Demographic information and clinical evaluation data, including the level of prognostic factors such as CRP, CEA, etc. will be published without mentioning the names of patients.

When the data will become available and for how long

One year after the end of the study it will be published and available in databases.

To whom data/document is available

If the funding sponsor allowed, the findings will be available for researchers, clinicians and scientific centers.

Under which criteria data/document could be used

The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable

For this purpose, you can contact with Sepideh Elyasi at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven, Mashhad, Iran. Email elyasis@mums.ac.ir

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

After receiving the query, dependent on the requested data, the scientific responsible person of the study will responsible to the query in coordinate with the sponsor within 2 weeks.

Comments