Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Capecitabin [Xeloda] + Oxaliplatin (XELOX) or Folinic acid + 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≥1.5×103/µL; Platelet count≥10×104/µL,hemoglobin≥9g/dL; Creatinine≤1.5 mg/dl; ALT,AST ≤5 ×ULN; total bilirubin≤2×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 thice 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)

Phone

+98 51 3180 1588

Email address

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≥9g/dL، Neutrophil count≥1.5×103/µL, Platelet count≥10×104/µLCreatinine≤1.5 mg/dl, ALT,AST ≤5 ×ULN، total bilirubin≤2×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

City

Mashhad

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 questionnare 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 clinicin'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
Imam Reza Hospital, Shariati Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3180 1588
Email
allahyaria@mums.ac.ir

2

Recruitment center
Name of recruitment center
Omid Hospital

Full name of responsible person
Sare Hosseini
Street address
Kouhsangi Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9176613775
Phone
+98 51 3180 1588
Email
hosseinis@mums.ac.ir

3

Recruitment center
Name of recruitment center
Qaem Hospital
Full name of responsible person
Hossein Rahimi
Street address
Qaem hospital, Ahmadabad Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3180 1588
Email
rahimih@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Faculty of Pharmacy, Ferdowsi University, Vakilabad boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1337
Email
tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Mahdi Jannati Yazdan Abad
Position
Clinical Pharmacy Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Ferdowsi University Campus, Vakil Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9415945344
Phone
+98 51 3180 1588
Fax
+98 51 3882 3251
Email
jannatim971@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Sepideh Elyasi
Position
Ph.D.
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Ferdowsi University campus, Vakil Abad Blvd., Mashhad
City
Mashhad

Province
Razavi Khorasan
Postal code
9415945344
Phone
+98 51 3180 1588
Fax
+98 51 3882 3251
Email
elyasis@mums.ac.ir

Person responsible for updating data

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
Street address
School of Pharmacy, Ferdowsi University Campus, Vakil Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9415945344
Phone
+98 51 3180 1588
Fax
+98 51 3882 3251
Email
jannatim971@mums.ac.ir

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