Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of oral formulation of Nano Silymarin efficacy, as an adjuvant to XELOX or FOLFOX regimen treatment for metastatic colorectal cancer: A triple blinded, randomized clinical trial

Protocol summary

Study aim
Evaluation of oral formulation of Nano Silymarin efficacy, as an adjuvant to XELOX or FOLFOX regimen treatment for metastatic colorectal cancer

Design
Clinical trial with control group with parallel groups, triple-blind, randomized, phase 2 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, Ghaem or Omid, with obtaining informed consent, they will enter the study. The capsules will be packaged in the factory and identified. Finally, they will be decrypted after completing the data collection.

Participants/Inclusion and exclusion criteria
Metastatic colorectal cancer without NRAS and KRAS mutation or no candidate for target 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
Intervention group: capsule nanosilymarin 70 mg prepared by Exiranano Sina company twice a day after meal during 6 21-day courses (XELOX or FOLFOX). Control group: placebo.

Main outcome variables
Periodic radiographic checks for metastatic extent CRP-CEA- CA19-9 RECIST1.1(Radiographic response of the tumor)

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: **IRCT20200408046990N5**
Registration date: **2020-12-17, 1399/09/27**
Registration timing: **prospective**

Last update: **2020-12-17, 1399/09/27**
Update count: **0**

Registration date
2020-12-17, 1399/09/27

Registrant information
Name
Sepideh Elyasi
Name of organization / entity
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Iran (Islamic Republic of)
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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 formulation of Nano Silymarin efficacy, as an adjuvant to XELOX or FOLFOX regimen treatment

for metastatic colorectal cancer: A triple blinded, randomized clinical trial

Public title
Evaluation of oral formulation of Nano Silymarin efficacy, as an adjuvant to XELOX or FOLFOX regimen treatment for metastatic colorectal cancer

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 financial incapacity) Under XELOX or FOLFOX regime treatment Patient consent to study Eastern cooperative oncology group (ECOG) 0/ 1 Hemoglobin≥9g/dL، Neutrophil count≥1.5×103/µL, Platelet count≥10×104/µL Creatinine≤1.5 mg/dl, ALT,AST ≤5 ×ULN، total bilirubin≤2×ULN

Exclusion criteria:
use of other antioxidant pregnancy or lactation history of allergy 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

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
With the help of a randomization list provided by randomization.com site, patients in the order of inclusion in the study will receive code 1 or 2 and will be included in placebo or medication group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Nano-silymarin and placebo soft gels packages in identical-looking 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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Mashhad

Province
Razavi Khorasan

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9415945344

Approval date
2020-11-17, 1399/08/27

Ethics committee reference number
IR.MUMS.REC.1399.503

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
Then 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
Then 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, 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, based on the doctor's clinical examination.

3

Description
Evaluation of the patient's liver status
Timepoint
At the beginning and end of six courses
Method of measurement
CTCAE v5, based on the doctor's clinical examination and sonography

Intervention groups

1

Description
Intervention group: Nanosiline Marine 70 mg capsule (softgel sinalive 70mg) prepared by Elixir Nanosina Company twice a day (after breakfast and dinner) for 6 21-day courses of XELOX or FOLFOX diet
Category
Treatment - Drugs

2

Description
Control group: Placebo with the same appearance prepared by Exiranano Sina Company twice a day (after breakfast and dinner) for 6 21-day courses of XELOX or FOLFOX diet
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center

Name of recruitment center
Gaem Hospital

Full name of responsible person
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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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Grant name

Grant code / Reference number

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
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Position
PHD student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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.
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