

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 $\geq 1.5 \times 10^3/\mu\text{L}$; 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

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

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 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 ≥ 9 g/dL, Neutrophil count $\geq 1.5 \times 10^3/\mu\text{L}$, Platelet count $\geq 10 \times 10^4/\mu\text{L}$ Creatinine ≤ 1.5 mg/dl, ALT, AST $\leq 5 \times \text{ULN}$, total bilirubin $\leq 2 \times \text{ULN}$

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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Province

Razavi Khorasan

Postal code

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

Abolghasem Allahyari

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2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Sare Hosseini

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3

Recruitment center

Name of recruitment center

Gaem Hospital

Full name of responsible person

Hossein Rahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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?**

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

Hedyieh Karbasforooshan

Position

PHD student

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**

Mashhad University of Medical Sciences

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Sepideh Elyasi

Position

PHD

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Hedyieh Karbasforooshan

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Latest degree

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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.

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