

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Assessment of the adjuvant ketogenic diet effect on therapeutic outcomes in metastatic colorectal cancer patients

Protocol summary

Study aim

Determining of the adjuvant ketogenic diet effect on therapeutic outcomes in metastatic colorectal cancer patients

Design

This randomized- parallel and open lable clinical trial study (phase 3) will be conducted on 42 metastatic colorectal cancer patients. Patients will be divided into ketogenic diet and control groups using block randomization method.

Settings and conduct

In this randomized- parallel and open lable clinical trial study, 42 metastatic colorectal cancer patients referred to oncology department of Urmia Imam Khomeini hospital will be enrolled. Patients in the intervention group will be received a ketogenic diet in addition to the standard chemotherapy protocol. The standard chemotherapy protocol will be implemented in the control group.

Participants/Inclusion and exclusion criteria

In this study, patients over 18 years of age with metastatic colorectal cancer will be included. Patients with lipid metabolism disorders such as carnitine deficiency, patients with liver failure, metastatic liver tissue more than 50%, a history of gastric and pancreatic surgery, renal cell carcinoma, type 1 diabetes won't be included.

Intervention groups

Patients in the intervention group will receive a ketogenic diet in addition to the standard chemotherapy protocol. The standard chemotherapy protocol will be implemented in the control group.

Main outcome variables

Response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210919052515N2**

Registration date: **2021-11-09, 1400/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-09, 1400/08/18**

Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Naser Masoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3337 9924

Email address

masoudi.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the adjuvant ketogenic diet effect on therapeutic outcomes in metastatic colorectal cancer patients

Public title
Adjuvant ketogenic diet and metastatic colorectal cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with stage 4 of colorectal cancer Age over 18 years
Exclusion criteria:
Lipid metabolism disorders such as carnitine deficiency
Patients with liver failure Metastasis to more than 50% in liver tissue History of gastric and pancreatic surgeries
Renal cell carcinoma Type 1 diabetes

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention and control groups using block randomization method. According to the total sample size (42 patients), 7 blocks of size 6 will be considered. (A: intervention group and B: control group). So that the all possible combinations of AAABBB will be listed. Then each combination will be given a number of one to seven. A number will be selected randomly for determination of one of the possible combinations. The randomization process will be continued until the last combination is enrolled. Patients will be divided into two groups according to the order of selected blocks.

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 Urmia University of Medical Sciences

Street address

Imam Khomeini Hospital, Ershad Ave, Modarres Blvd

City

Urmia
Province
West Azarbaijan
Postal code
57157 81351

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.UMSU.REC.1400.140

Health conditions studied

1

Description of health condition studied

Colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

Primary outcomes

1

Description

Response to treatment including primary tumor and metastasis size before and after the intervention

Timepoint

Before and three months after the intervention.

Method of measurement

With CT scan imaging in millimeters

Secondary outcomes

1

Description

Ketone body

Timepoint

Before and three months after the intervention

Method of measurement

Ketone meter in blood serum (mM/L)

2

Description

Carcinoembryonic antigen (CEA)

Timepoint

Before and three months after the intervention

Method of measurement

ELISA test (ng/mL)

3

Description

Vascular endothelium growth factor expression (VEGF)

Timepoint

Before and three months after the intervention

Method of measurement

Blood serum (Pg/mL)

4

Description

C-Reactive Protein (CRP)

Timepoint

Before and three months after the intervention

Method of measurement

Blood serum (mg/L)

Intervention groups

1

Description

Intervention group: Patients will be received the ketogenic diet for three months in addition to the standard chemotherapy protocol. The ketogenic diet is a low-carb, high-fat diet. The ratio of macronutrients in this diet: 75% fat, 15 to 20% protein, 5 to 10% carbohydrates. The nutritionist will explain to the patients about the diet, then the manuals of this diet will be provided to patients. Patients will be followed by telephone for diet compliance.

Category

Treatment - Other

2

Description

Control group: In the control group, only the standard chemotherapy protocol will be implemented for patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Educational hospital

Full name of responsible person

Dr. Naser Masoudi

Street address

Imam Khomeini Educational hospital, Ershad Ave,
Modarress Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

dr.nasmasoudi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences, Resalat Ave,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 1930

Email

mohebbi.i@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Naser Masoudi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3337 9924

Email

dr.nasmasoudi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Naser Masoudi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Ershad Ave, Modarress Blvd,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

dr.nasmasoudi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Naser Masuodi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital, Ershad Ave, Modarress Blvd,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3345 9538

Email

dr.nasmasuodi@gmail.com

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data is probably to be shared in the Iranian
ketogenic registry.

When the data will become available and for how long

After the publishing of article

To whom data/document is available

Researchers

Under which criteria data/document could be used

as published article

From where data/document is obtainable

Corresponding author

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

If necessary through e-mail addresses of corresponding
author in the published article can have access to the
data.

Comments