Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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.
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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.
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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
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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
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
Coressponding 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