Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the tolerability of the diet containing CAPRIDIN in patients with rectal cancer undergoing chemoradiotherapy

Protocol summary

Study aim
Investigating the tolerability of the diet containing CAPRIDIN in patients with rectal cancer undergoing chemoradiotherapy

Design
A clinical trial with a control group, with parallel, blinded, randomized and phase 1-2 groups on 20 patients.

Settings and conduct
A number of 20 patients, who refer to the Radiotherapy Clinic of the Cancer Institute of IKHC due to non-metastatic rectal cancer, will be evaluated by a specialist according to the inclusion criteria and entered the project after signing the consent form. All patients receive standard chemoradiation treatment. After the face-to-face training session, the intervention group consumes Capridin product produced by HealthWeX Company (Canada) for an average of 6 weeks, (30 cc daily on overage an empty stomach). The intervention group is advised to limit carbohydrate sources in their daily diet. In order to reduce the sources of food carbohydrates, the patients will be given a general recipe. The control group will also be given the same amount of placebo and the same nutritional recommendations will be given.6 weeks after the end of chemoradiotherapy, patients undergo MRI of the pelvis to evaluate the clinical response. Between the end of radiotherapy and MRI, all patients undergo a course of chemotherapy with XELOX regimen.

Participants/Inclusion and exclusion criteria
Non-pregnant and non-lactating patients with non-metastatic rectal adenocarcinoma candidates for chemoradiotherapy aged 18-75 years and without underlying disease with BMI: 18-34

Intervention groups
Patients who take 30 cc of CAPRIDIN fasting on average for 6 weeks in addition to the standard rectal cancer treatment. The control group also receives the standard treatment of rectal cancer and instead of CAPRIDIN, it receives the same amount of placebo for an average of one week.

Main outcome variables
Tolerability, side effects, clinical response and serum ketone levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170211032494N4**
Registration date: **2023-08-15, 1402/05/24**
Registration timing: **prospective**

Last update: **2023-08-15, 1402/05/24**
Update count: **0**

Registration date
2023-08-15, 1402/05/24

Registrant information

Name
Nima Mousavi Darzikolaee

Name of organization / entity
Radiation Oncology Research Center, Cancer Institute, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the tolerability of the diet containing CAPRIDIN in patients with rectal cancer undergoing chemoradiotherapy

Public title
Investigating the tolerability of a diet containing CAPRIDIN in patients with rectal cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 75 years old Patients with definitive diagnosis of rectal adenocarcinoma according to histopathology Patients with a Karnofsky score higher than 70 Non-metastatic patients Locally advanced patients (T3, T4) N0 or N+ Patients with BMI between 18-34
Exclusion criteria:
Patients with metabolic diseases Pregnancy Liver or kidney dysfunction Receiving neoadjuvant chemotherapy Patients who have undergone rectal cancer surgery for any reason Breastfeeding No previous ketogenic diet
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
"Random Allocation V.2" software is used for randomization. This software can be downloaded from the following link: https://random-allocation-software.software.informer.com Patients will be allocated in two intervention and control groups in equal numbers. For randomization, the block randomization method was used, which defines blocks of four, and the order of assigning houses to each group is based on random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and their companions, all the people who are involved in patient registration, doctors, nurses and anyone who is in contact with the patient in the process of treatment and care, and the research team are all kept blind to the prescription and consumption of capridin or placebo. The order of the patient's entry is recorded on the envelopes with the patient's code. Codes are also recorded on bottles containing capridin. After the patient has been examined by the doctor in terms of the criteria for entering the study, according to the order of referral, the desired envelope is opened and the code related to the intervention is determined. Based on the code, the bottle of the same code (capridine or placebo) is given to the patient. In this way, the patient is unaware that he is receiving capridine or a placebo
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Working Group/Ethics Committee in Research of Imam Khomeini Hospital Complex, Tehran University of M
Street address
Imam Khomeini hospital complex; Qarib Ave; Keshavarz Blvd; Tehran
City
tehran
Province
Tehran
Postal code
1419733141
Approval date
2022-12-20, 1401/09/29
Ethics committee reference number
IR.TUMS.IKHC.REC.1401.272

Health conditions studied

1

Description of health condition studied
Rectal cancer, Ketogenic regimen
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

Primary outcomes

1

Description
Tolerability: not interrupting the ketogenic diet for more

than 4 consecutive days or 8 non-consecutive days

Timepoint

Every four days for 6 weeks

Method of measurement

Medical history taking

2

Description

Complications: reports of gastrointestinal discomfort, nausea, vomiting, lethargy, constipation, diarrhea by the patient

Timepoint

Every week for 6 weeks

Method of measurement

Medical history taking

3

Description

Serum ketones: the amount of ketones released in the blood

Timepoint

Before starting the study and every day for 6 weeks

Method of measurement

ketometery

Secondary outcomes

1

Description

Clinical response: T, N stage based on MRI

Timepoint

6 weeks after the end of radiotherapy

Method of measurement

Doing pelvic MRI

Intervention groups

1

Description

Patients who take 30 cc of CAPRIDIN fasting on average for 6 weeks in addition to the standard rectal cancer treatment. Capridin is a product of HealthWeX (Canada) that contains medium chain fatty acids. These compounds are used in ketogenic diets and induce ketogenesis. Treatments based on ketogenesis in the control of epilepsy are among the approved treatments for this disease.

Category

Treatment - Drugs

2

Description

Patients who take 30 cc of placebo daily on an average for 6 weeks in addition to the standard rectal cancer treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

imam Khomeini hospital complex

Full name of responsible person

Nima Mousavi Darzikolaee

Street address

Imam Khomeini hospital complex, Qarib Ave., Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

6th floor, Central Organization of Tehran University of Medical Sciences, corner of Qods St., Keshavarz Blvd.

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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

Tehran 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
Hamedan University of Medical Sciences

Full name of responsible person
Reyhaneh Bayani

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran

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Person responsible for scientific inquiries

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Person responsible for updating data

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Mabediniparizi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Informed consent form

When the data will become available and for how long
From the beginning of October 2025 onwards

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
No decision has been made regarding the release of non-personally identifiable data or other documentation, and the release schedule is not yet known

From where data/document is obtainable
For contact, it is possible to refer to the following address: Cancer Radiation Therapy Research Center (Cancer Institute) - Imam Khomeini Hospital Complex - End of Keshavarz Blvd. - Doctor Gharib Street - Tehran - Iran - Postal Code: 1419733141

What processes are involved for a request to access

data/document

If the decision to publish non-identifiable personal data or other documents is finalized, the applicant can contact the responsible author or executives by referring to the cancer radiation therapy research center (Cancer Institute) - from October 2025 onwards - ask to receive their contact information from the mentioned center. The mentioned information will be provided to the applicant via email at most one month after contacting the center.

Comments