Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

A clinical trial comparing a very low carbohydrate MCT oil supplemented diet with standard diet on prognostic biomarkers and indicators related to cachexia in gastric adenocarcinoma patients.

Protocol summary

Summary

This study have been designed in order to compare the prognostic biomarkers and indicators related to cachexia in two groups of Gastric adenocarcinoma patients which consume a “very low carbohydrate high fat MCT oil supplemented diet” and a “standard diet”. Study design: randomized, single-center, controlled trial without blinding. Methods: after signing the informed consent 20 patients with gastric adenocarcinoma in 0-4 ECOG score which have not been gastrectomized, will be allocated randomly into control and intervention groups (intervention=10 N, control=10 N). Exclusion criteria are consist of: Diabetes, recipients of insulin or any anabolic drugs, less than 90% adherence of diets, and incidence of hypoglycemia during the intervention. Patients in intervention group are recipients of an Isocaloric low carbohydrate high fat MCT oil supplemented diet. The control group will be given an Isocaloric standard diet without changing the normal dietary components. In both groups the intervention lasts up to 6 weeks. Information will be collected at the beginning and end of the study. These variables are: weight, body mass index, resting energy expenditure, and body composition measurements. In order to evaluate the patients' performance status changes the Karnofsky scale and ECOG scoring observational methods will be used. Twenty cc of blood samples will be collected in two steps (in the beginning day and 42 days later) to evaluate ca 19-9, CEA, high sensitivity C-reactive protein, ketone bodies, fasting blood glucose, serum insulin, complete blood count and differential, serum lactate, and serum albumin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102830538N1**
Registration date: **2016-12-20, 1395/09/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-20, 1395/09/30

Registrant information

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Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing a very low carbohydrate MCT oil

supplemented diet with standard diet on prognostic biomarkers and indicators related to cachexia in gastric adenocarcinoma patients.

Public title
The effect of very low carbohydrate and high fat diet on gastric cancer
Purpose
Treatment
Inclusion/Exclusion criteria
(Inclusion criteria: diagnosis of gastric adenocarcinoma; patients with ECOG performance status of 0 to 4; patients who have not been gastrectomized; blood, liver, and kidney should be functional; patients aged 18 years and older; both genders will be recruited; leucocytes count be over 3000 cell in each mm3 of blood; neutrophil count be over 1500 cubic millimeter of blood; platelets be over 1500 per each cubic millimeter of blood; total bilirubin lower than 3mg/dL; serum creatinine lower than 2mg/dL; serum potassium less than 5 mmol/L). (Exclusion criteria: Patients which live alone during the intervention without others attendance; Diabetes; patients receiving Insulin or other anabolic drugs along with intervention; pyruvate dehydrogenase complex deficiency; and inherited porphyria ; MCT oil consumption until 5 weeks before recruitment in study; Having congestive heart failure; Uncontrolled hypertension. Severe steatorrhea and diarrhea; Gastrointestinal obstruction; Patients which could not resist the intervention for any reason; Frequent incidence of hypoglycemia during first week of intervention).
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Tehran University of Medical Sciences
Street address
Room 605, 6th floor, Central building of Tehran University of Medical Sciences, Quds St, Keshavarz Blvd. Tehran
City
Tehran
Postal code
Approval date
2016-07-25, 1395/05/04
Ethics committee reference number
IR.TUMS.VCR.REC.1395.352

Health conditions studied

1

Description of health condition studied
Gastric cancer
ICD-10 code
c16
ICD-10 code description
Malignant neoplasm of stomach

Primary outcomes

1

Description
Carcinoembryonic antigen (CEA)
Timepoint
Before and after intervention
Method of measurement
ELISA

2

Description
Ca19-9
Timepoint
Before and after intervention
Method of measurement
ELISA

3

Description
Serum ketone bodies
Timepoint
Before and after intervention
Method of measurement
Spectrophotometer

4

Description
FBS
Timepoint
Before and after intervention
Method of measurement

Spectrophotometer

5

Description
Body Mass Index (BMI)
Timepoint
Before and after intervention
Method of measurement
Formula

6

Description
Hs-CRP
Timepoint
Before and after intervention
Method of measurement
Auto analyzer

Secondary outcomes

1

Description
Insulin
Timepoint
Before and after intervention
Method of measurement
Auto analyzer

2

Description
Resting energy expenditure (REE)
Timepoint
Before and after intervention
Method of measurement
Gathering the produced CO2 by indirect calorimetry

3

Description
HOMA-IR
Timepoint
Before and after intervention
Method of measurement
Is calculated by the formula

4

Description
Serum Lactate
Timepoint
Before and after intervention
Method of measurement
Auto analyzer

5

Description
CBC-diff
Timepoint
Before and after intervention
Method of measurement
Complete blood count and differential

6

Description
Serum Albumin
Timepoint
Before and after intervention
Method of measurement
Auto analyzer

7

Description
Karnofsky score
Timepoint
Before and after intervention
Method of measurement
Observation

8

Description
Eastern Cooperative Oncology Group (ECOG)
Timepoint
Before and after intervention
Method of measurement
Observation

9

Description
Bioelectric Impedance Analysis (BIA)
Timepoint
Before and after intervention
Method of measurement
Weight

Intervention groups

1

Description
Intervention group receives an Isocaloric diet with low carbohydrate content. Dietary components will change weekly in order to increase MCT oil consumption. The carbohydrates are limited to 10 to 15% of daily energy intake. Proteins are 20 to 30% of energy, fats are 45 to 55% of daily energy, and remaining energy will be supplied by MCT oil 15 to 30% with a gradually increasing method.
Category
Treatment - Other

2

Description
Patients in the control group are recipients of an Isocaloric standard diet with the normal dietary components based on their dietary requirements.
Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hematology Oncology and Stem Cell Research Center

Full name of responsible person

Street address
Hematology Oncology and Stem Cell Research Center , Shariati Hospital, North Karegar street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of research, International Campus, Tehran University of Medical Sciences

Full name of responsible person
Vice chancellor for research

Street address
No. 124, Third Floor, International Campus, Northern Baradaran-Mozafar St, Vali Asr St, Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor of research, International Campus, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person
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Position
MS.c candidate of nutritional sciences

Other areas of specialty/work

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Full name of responsible person
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Position
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty