

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

Name

Alireza Dadfar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 88896696

Email address

adadfar@razi.tums.ac.ir

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

Alireza Dadfarma

Position

MS.c candidate of nutritional sciences

Other areas of specialty/work

Street address

No.44, Hojjat-dost Alley, Naderi St, Keshavarz Blvd,
Tehran

City

Tehran

Postal code

Phone

+98 21 8895 5975

Fax

Email

adadfar@razi.tums.ac.ir; alireza.da89@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Saeed Hosseini

Position

Nutritionist and Dietitian, Associate Professor

Other areas of specialty/work

Street address

No 44, 5th floor, Clinical nutrition department, Hojjat-dost Alley, Naderi St, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Phone

+98 21 8895 5975

Fax

Email

saeedhmdphd@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Full name of responsible person

Alireza Dadfarma

Position

MS.c candidate of nutritional sciences

Other areas of specialty/work

Street address

No. 44, Hojjat-dost Alley, Naderi St, Keshavarz Blvd,
Tehran

City

Tehran

Postal code

Phone

+98 21 8895 5975

Fax

Email

adadfar@razi.tums.ac.ir; alireza.da89@gmail.com

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