Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study on the effect of ω-3 fatty acids supplementation on nutritional status, some inflammatory factors and matrix metalloproteinases in gastric cancer patients undergoing chemotherapy

Protocol summary

Summary

Background: Gastric cancer is the fourth most common cancer in the world, the second most common cancer in Asia and the second leading cause of death among cancers in the worldwide, that the many factors are involved. Consumption of ω-3 fatty acids supplementation inhibits oxidative stress injury, prevention of cachexia , improve of appetite and reduce of the amount of matrix metaloproteinase enzyme activity in gastric cancer patients. The aim of this study is determination of the effect of ω-3 fatty acids supplementation on nutritional status, some inflammatory factors and matrix metaloproteinase in gastric cancer patients undergoing chemotherapy. Methods: In this study 15 volunteers patients with gastric cancer receiving chemotherapy for cases and 15 volunteers patients for controls are selected by Randomized allocation. Demographic, anthropometric factors, and nutritional information will be collected for patients and changes of weight, BMI, calories and nutrients intake will be calculated for both groups. 3 g of ω-3 fatty acid supplementation for intervention group and placebo for control group will be given for 45 days. Then blood samples in three stages (in the beginning, 30 and 45 days after interval) will be collected to test 2 and 9 matrix metaloproteinases, hepatic acute phase protein, malondialdehyde, tumor necrosis factor-α, interlukin 1, 2 and 6, total antioxidant capacity, blood albumin, serum iron and blood fats.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011095144N1**
Registration date: **2011-01-28, 1389/11/08**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-01-28, 1389/11/08

Registrant information

Name
Ali Nemati
Name of organization / entity
Ardabil University of Medical Sciences
Country
Iran (Islamic Republic of)
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a.nemati@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-05-22, 1389/03/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the effect of ω-3 fatty acids supplementation on nutritional status, some inflammatory factors and matrix metalloproteinases in gastric cancer patients undergoing chemotherapy

Public title

Effect of ω-3 fatty acids on gastric cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with gastric cancer in phase 3 (cardia and non cardia) during chemotherapy over 30 years old. Exclusion criteria: other diseases induced cachexia such as heart disease, lung, AIDS, renal disease, incidence of acute leukemia, diabetes and multiple myeloma, individauls undergoing surgery and who do not take the given drugs properly during the study period.

Age

From **30 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor of Research in Tabrizl University of medical sciences

Street address

Vice Chancellor of Research, Tabriz University of medical sciences, Daneshgah St.

City

Tabriz

Postal code

Approval date

2010-12-01, 1389/09/10

Ethics committee reference number

1389-09-10

Health conditions studied

1

Description of health condition studied

Gastric cancer patients undergoing chemotherapy

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

weight

Timepoint

days of 0, 30 and 45

Method of measurement

digital scale

Secondary outcomes

1

Description

Body Mass Index

Timepoint

days of 0, 30 and 45

Method of measurement

measured by ratio of weight (kilograms) to squared height (m)

2

Description

daily calorie intake

Timepoint

days of 0, 30 and 45

Method of measurement

24 hour recall questionnaire

3

Description

daily nutreints intake

Timepoint

days of 0, 30 and 45

Method of measurement

24 hour recall questionnaire

4

Description

Nausea

Timepoint

days of 0, 30 and 45

Method of measurement

quaistionnaire

5

Description

Vomiting

Timepoint
days of 0, 30 and 45
Method of measurement
quaistionnaire

6

Description
Appetite
Timepoint
days of 0, 30 and 45
Method of measurement
quaistionnaire

7

Description
dairreha
Timepoint
days of 0, 30 and 45
Method of measurement
quaistionnare

8

Description
abdominal cramp
Timepoint
days of 0, 30 and 45
Method of measurement
quaistionnaire

9

Description
total antioxidant
Timepoint
days of 0, 30 and 45
Method of measurement
spectrophotometry

10

Description
MDA
Timepoint
days of 0, 30 and 45
Method of measurement
spectrophotometry

11

Description
interleukin1
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

12

Description
interleukin 6
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

13

Description
interleukin 2
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

14

Description
TNF-α
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

15

Description
mmp9
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

16

Description
mmp2
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

17

Description
cholestrol
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

18

Description
triglyceride
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

19

Description
TIBC
Timepoint
days of 0, 30 and 45

Method of measurement
autoanalyzer

20

Description
Blood albumin
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

21

Description
LDL- C
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

22

Description
HDL-C
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

23

Description
Blood iron
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

24

Description
CRP
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

25

Description
proxonaz 1
Timepoint
days of 0, 30 and 45
Method of measurement
spectophotometry

26

Description
IgA
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

27

Description
IgG
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

28

Description
IgM
Timepoint
days of 0, 30 and 45
Method of measurement
ELISA

29

Description
transferrin
Timepoint
days of 0, 30 and 45
Method of measurement
autoanalyzer

Intervention groups

1

Description
Interventions 1: ω-3 fatty acids, 3 g daily for 45 days
Category
Treatment - Drugs

2

Description
interventions2: rice powder, three capsules daily for 45 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Aras clinic of Imam Hospital
Full name of responsible person
Ali Nemati
Street address
Ardabil University of Medical Sciences
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutririon research center
Full name of responsible person
Dr. Alireza ostadrahimi
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Nutrition research center, faculty of Health & Nutrition, Atar-Neishaboori st, Golgasht st
City
Tabriz
Grant name
1389-10-7
Grant code / Reference number
07-10-1389
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutririon research center
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

Person responsible for scientific inquiries

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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