

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Study on the effect of $\omega$ -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  $\omega$ -3 fatty acids supplementation inhibits oxidative stress injury, prevention of cachexia, improve of appetite and reduce of the amount of matrix metalloproteinase enzyme activity in gastric cancer patients. The aim of this study is determination of the effect of  $\omega$ -3 fatty acids supplementation on nutritional status, some inflammatory factors and matrix metalloproteinase 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  $\omega$ -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 metalloproteinases, hepatic acute phase protein, malondialdehyde, tumor necrosis factor- $\alpha$ , interleukin 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)

###### Phone

+98 45 3351 0052

###### Email address

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  $\omega$ -3 fatty acids supplementation on nutritional status, some inflammatory factors and matrix metalloproteinases in gastric cancer patients undergoing chemotherapy

##### Public title

Effect of  $\omega$ -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, individuals 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 Tabriz 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 nutrients 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

questionnaire

### 5

#### Description

Vomiting

**Timepoint**  
days of 0, 30 and 45  
**Method of measurement**  
questionnaire

## 6

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

## 7

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

## 8

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

## 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- $\alpha$   
**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**  
cholesterol  
**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**

spectrophotometry

## 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:  $\omega$ -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**

Nutrition research center

**Full name of responsible person**

Dr. Alireza ostadrahimi

**Street address**

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**

Nutrition 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

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Nemati

**Position**

M.Sc. in nutrition

**Other areas of specialty/work**

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Basic Science group, Faculty of Medicine, Ardebil University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Nemati

**Position**

Ph.D Student/ faculty member

**Other areas of specialty/work**

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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*