

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid on lipoprotein profile & tumor necrosis factor- α in patients with helicobacter pylori Infection

Protocol summary

Summary

The objective of this study is to compare the effect of Eicosapentaenoic Acid and Docosahexaenoic Acid on serum lipoprotein profile. In this double blind placebo controlled randomized clinical trial, 105 patients with Helicobacter pylori infection, without history of infection & pharmaceutical treatment, will be selected and received pharmaceutical treatment of infection eradication for 2 weeks. For another 10-week period (totally 12 weeks), the patients in the control group received 2 gr MCT placebo daily, in the second group received 2 gr moreEPA supplement daily and the patients in the third group received 2 gr moreDHA supplement daily. After 12 weeks, level of serum TC, LDL-C, HDL-C, TG & TNF- α will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205262709N25**

Registration date: **2012-07-07, 1391/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-07, 1391/04/17

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Gastrointestinal & Liver Disease Research Center of Tehran University of Medical Sciences- Firoozgar

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid on lipoprotein profile & tumor necrosis factor- α in patients with helicobacter pylori Infection

Public title

The comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid in patients with helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: positive helicobacter pylori test result; no history of pharmaceutical treatment for infection eradication; no gastric surgery; no history of peptic ulcer; no any disease that cause inflammation & increase of serum inflammatory markers level such as diabetes,

CVD, respiratory inflammations such as asthma,...; no consumption of any drug other than prescribed drugs during the study; no consumption of antibiotic or bismut during 2 months before the trial; no consumption of antioxidant supplements such as Se, Zn, beta-caroten,... at least 3 months before the trial; no consumption of omega-3 supplements at least 3 months before the trial; no smoking; BMI less than 30; age between 20-60 years old; leaning to cooperation Exclusion criteria: no leaning to continuing the cooperation; any change in type or dose of prescribed drugs; any change in daily diet or physical activity; consumption of any antioxidant supplement; consumption of less than 70% of supplements given to patients at the start of the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

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

School of Public Health of Tehran of University of Medical Sciences

Street address

Number 60, Alvand Street, Argentina Square

City

Tehran

Postal code

1516846515

Approval date

2010-10-10, 1389/07/18

Ethics committee reference number

2402

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

ICD-10 code

k27

ICD-10 code description

Peptic ulcer, site unspecified

Primary outcomes

1

Description

total cholesterol

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

enzymatic colorimetry

2

Description

LDL-C

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

immunoturbidometry

3

Description

HDL-C

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

immunoturbidometry

4

Description

TG

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry

5

Description

TNF-alfa

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

enzymatic colorimetry

Secondary outcomes

empty

Intervention groups

1

Description

intervention 1 group : daily 2 gr morEPA supplement during 12 weeks

Category

Treatment - Drugs

2

Description

intervention 2 group : daily 2 gr morDHA supplement during 12 weeks

Category

Treatment - Drugs

3

Description

control group : daily 2 gr MCT placebo during 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Dr Shahram Agah

Street address

Niyayesh street, Sttar khan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gastrointestinal & Liver Disease Research Center (Firoozgar GILDRC)

Full name of responsible person

Dr Shahram Agah

Street address

Behafarin street, Valiasr square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gastrointestinal & Liver Disease Research Center (Firoozgar GILDRC)

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 Public Health of Tehran University of Medical Sciences

Full name of responsible person

Dr Farzad Shidfar

Position

Professor Assistant/nutrition PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Farzad Shidfar

Position

Professor Assistant/nutrition PhD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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