

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Comparison of The Effect of Eicosapentaenoic Acid and Docosahexaenoic Acid on Helicobacter pylori Infection Eradication and Some Serum Inflammatory Factors

Protocol summary

Summary

The objective of this study is to compare the effect of Eicosapentaenoic Acid and Docosahexaenoic Acid on Helicobacter pylori infection eradication and some serum inflammatory factors. 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, infection eradication rate and level of serum inflammatory factors such as hs-CRP, IL-6, IL-8, and TAC will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101122709N16**
Registration date: **2011-02-13, 1389/11/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-13, 1389/11/24

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8862 2755

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Recruitment status

Recruitment complete

Funding source

Faculty of Public Health of Tehran University of Medical Sciences

Expected recruitment start date

2011-01-30, 1389/11/10

Expected recruitment end date

2011-05-31, 1390/03/10

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 Helicobacter pylori Infection Eradication and Some Serum Inflammatory Factors

Public title

The Comparison of The Effect of Eicosapentaenoic Acid and Docosahexaenoic Acid on Helicobacter pylori Infection Eradication and Some Serum Inflammatory Factors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - positive stool antigen 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**

Faculty of Public Health of Tehran University of
Medical Sciences

Street address

Number 60, Alvand street, Argentina square, Tehran

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

K25

ICD-10 code description**Primary outcomes****1****Description**

Helicobacter pylori infection eradication

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

stool antigen test

2**Description**

serum level of Il-6

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ELISA kitt

3**Description**

serum level of Il-8

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ELISA kitt

4**Description**

serum level of hs-CRP

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

ELISA kitt

5**Description**

serum level of TAC

Timepoint

before & after intervention (after 12 weeks intervention)

Method of measurement

colorimetry (FRAP)

Secondary outcomes

empty

Intervention groups

1

Description

control group : MCT supplement, 2 grams per day (twice a day, each time 1 gram), at morning and evening, and during 12 weeks

Category

Placebo

2

Description

intervention 1 group : moreEPA supplement, 2 gram per day (twice a day, each time 1 gram) at morning and evening, and during 12 weeks

Category

Treatment - Drugs

3

Description

intervention 2 group:moreDHA supplement, 2 grams per day (twice a day, each time 1 gram), at morning and evening, and during 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Honor Rasool Akram therapeutic educational center

Full name of responsible person

Dr Shahram Agah

Street address

Sttar khan - Niyayesh street

City

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Dr Shahram Agah

Street address

Valiasr square - Behafarin street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vive-chancellor for Research, Tehran University of

Medical Sciences

Full name of responsible person

Dr Seyyed Abbas Motevalian

Street address

Keshavarz Bld - intersection of Qods street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vive-chancellor for Research, Tehran University of
Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Gastrointestinal & Liver Disease Research Center
(Firoozgar GILDRC)

Full name of responsible person

Dr Shahram Agah

Street address

Valiasr square - Behafarin street

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

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

Faculty of Public Health of Tehran University of

Medical Sciences

Full name of responsible person

Dr Farzad Shidfar

Position

Professor /nutrition PhD

Other areas of specialty/work

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Dr Farzad Shidfar

Position

Professor /nutrition PhD

Other areas of specialty/work

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