

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of of Polyunsaturated Fatty Acids on the Nitrosative Stress of Patients Infected With Helicobacter pylori With Dyspeptic Symptoms

Protocol summary

Study aim

Effect of omega fatty acids on nitrosative stress in patients infected with Helicobacter pylori with dyspeptic symptoms

Design

This study is a clinical trial of double-blinded study involving a target population of 34 patients infected with Helicobacter pylori with dyspeptic symptoms. Ping pong balls were used to randomize and assign patients to two control groups (17 people) and intervention (17 people).

Settings and conduct

In this study, neither the physician nor the patient was aware of the allocation of patients to the target groups, and the method of blinding was random and using ping pong balls. The experiments were done in department of clinical biochemistry of Medical Faculty of Tabriz University of Medical Sciences. The control group received standard therapy and the intervention group received standard therapy plus omega capsules for two weeks. To measure the nitric oxide content of gastric juice in the fasting state, gastric juice was enrolled and the NO amount was measured using the Griess Colorimetric method.

Participants/Inclusion and exclusion criteria

Included: presence of peptic ulcer and infected to H. pylori
Excluded: In this study people with gastric adenocarcinoma, diabetics, patients with kidney problems, smokers, and patients who had taken omega, fish, drugs, or other medications and supplements three months before entering the study, were excluded.

Intervention groups

The study included two control and intervention groups that, in order to evaluate the effectiveness of omega-3 fatty acids, received the standard therapy intervention group plus omega capsule tablets, and the control group received only the standard therapy. Standard therapy includes clarithromycin, amoxicillin, and metronidazole

Main outcome variables

Nitric Oxide Reduction of stomach juice in H.pylori

infected patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031338N3**

Registration date: **2020-07-14, 1399/04/24**

Registration timing: **retrospective**

Last update: **2020-07-14, 1399/04/24**

Update count: **0**

Registration date

2020-07-14, 1399/04/24

Registrant information

Name

rasoul sharifi

Name of organization / entity

university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-10-12, 1394/07/20

Actual recruitment start date

2015-04-21, 1394/02/01

Actual recruitment end date

2015-10-12, 1394/07/20

Trial completion date

2016-08-22, 1395/06/01

Scientific title

The Effect of Polyunsaturated Fatty Acids on the Nitrosative Stress of Patients Infected With Helicobacter pylori With Dyspeptic Symptoms

Public title

Polyunsaturated Fatty Acids and With Helicobacter pylori

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

infection ti H. pylori presence of active peptic ulcer

Exclusion criteria:

subjects with gastric cancer subjects with diabetes subjects with renal disease Subjects who had used fattyacid supplements three months before the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Write the numbers 1 and 2 in 17 on ping pong balls and pick up the balls by the participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using random numbers The allocation of individuals was done randomly by the researcher and by lottery in case or control groups to avoid possible errors and unwanted orientations. The allocation was made by throwing 34 ping pong balls into a cloth bag, 17 of which were standard therapy + omega capsules, and 17 of which were standard. Each patient who returned to the physician would pick up a ping pong ball, thus identifying the patient group and throwing the balls away after selection.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

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Golgasht Street;

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5165665931

Approval date

2015-10-26, 1394/08/04

Ethics committee reference number

TBZMED.REC.1394.641

Health conditions studied**1****Description of health condition studied**

peptic ulcer

ICD-10 code

K27.7

ICD-10 code description

Chronic peptic ulcer, site unspecified, without hemorrhage or perforation

Primary outcomes**1****Description**

Nitric Oxide

Timepoint

after treatment

Method of measurement

Griess Colorimetric Method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group received standard therapy plus omega capsules for two weeks. These capsules were NaturalFactors Ultimate-Omega Factors 90 Soft gels (SKU 2260)and each soft gel contains a total of 1200 mg of fatty acid derived from molecular distilled, ultra-purified fish oil,(400 mg) containing EPA (120 mg), DHA (80 mg), organic faxseed seed oil (400 mg) containing ALA (200 mg), OLA(60 mg) and borage seed oil (400 mg), GLA (75 mg) and OLA (55 mg).Follow-up medication and omega-3 capsules were

monitored by a specialist by telephone.

Category

Treatment - Drugs

2**Description**

Control group: The control group received standard therapy recipients, namely clarithromycin, amoxicillin and nitromidazole. The medication was monitored by a specialist doctor by telephone. Clarithromycin 250 mg daily, amoxicillin half a gram daily, and omeprazole 10 mg daily. Consumption period was 2 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Dr.Shirmohammadi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

70

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Homayun Doatkahh

Position

CLERK

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

via email

When the data will become available and for how long

any time

To whom data/document is available

all Academic Person

Under which criteria data/document could be used

for keep on study

From where data/document is obtainable

Rasoul Sharifi

What processes are involved for a request to access data/document

communication via email

Comments