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

n 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 infedted 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)

Phone

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Email address

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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 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
Street address
Golgasht Street;
City
tabriz
Province
East Azarbaijan
Postal code
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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Sponsors / Funding sources

1

Sponsor

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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 Doatkhah

Position
CLERK

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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lecturer and employee

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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