Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Oct 2026

Effects of concurrent Omega-3 and Cranberry juice consumption on eradication of Helicobacter pylori, gastrointestinal symptoms, some serum inflammatory and oxidative stress markers in adults with Helicobacter pylori infection

Protocol summary

Study aim

Effects of Omega 3 and Cranberry juice consumption on eradication of Helicobacter pylori, serum inflammatory and oxidative stress markers in adults with Helicobacter pylori infection

Design

Ninety-Two patients referred to the liver and gastroenterologist with gastrointestinal complaints will be allocated into one of the three intervention groups or the control group using a randomized blocked division.

Settings and conduct

Adults referred to the liver and gastroenterologist of Soroush Clinic in Ahvaz in 1396

Participants/Inclusion and exclusion criteria

Inclusion criteria including age between18 to 65 years old, infection with Helicobacter pylori, gastrointestinal complaints and body mass index of 18.5 to 35 kg /m2. Exclusion criteria including any gastrointestinal and chronic diseases,taking medications, omega-3 and any dietary supplements at least 3 months before starting the study and the consumption of less than 80 percent of the supplements delivered to the patient during the study period.

Intervention groups

Intervention group 1: Two weeks taking Pentoprazole 80 mg , Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g and Cranberry juice (400 ml) enriched with omega 3 (2 g) for 4 weeks Group 2: Two weeks taking Pentoprazole 80 mg , Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g and Cranberry juice (400 ml) for 4 weeks Group 3:Two weeks taking Pentoprazole 80 mg , Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g and omega 3 (two grams) for 4 weeks Control group: Two weeks taking Pentoprazole 80 mg, Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g for two weeks.

Main outcome variables

Negative anti-Helicobacter pylori antigen; Determination and comparison of Helicobacter pylori caused gastrointestinal complaints questionnaire scale; serum levels of interleukin17, Transforming growth factor beta 1, Interferon gamma and serum levels of total antioxidant capacity and malondialdehyde

General information

Reason for update

Change the sampling completion date. Due to the lack of timely completion of the intervention due to sanctions, sampling was delayed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025274N3**
Registration date: **2018-01-28, 1396/11/08**
Registration timing: **prospective**

Last update: **2020-04-15, 1399/01/27**
Update count: **1**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Ahmad Zare Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-01-29, 1396/11/09
Expected recruitment end date
2020-09-21, 1399/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of concurrent Omega-3 and Cranberry juice consumption on eradication of Helicobacter pylori, gastrointestinal symptoms, some serum inflammatory and oxidative stress markers in adults with Helicobacter pylori infection

Public title
Effects of concurrent Omega-3 and Cranberry juice consumption on eradication of Helicobacter pylori, gastrointestinal symptoms, some serum inflammatory and oxidative stress markers in adults with Helicobacter pylori infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years old Helicobacter pylori infection Gastrointestinal complaints Body mass index 18.5 to 35 kg / m2
Exclusion criteria:
Having a history of drug therapy to eradicate Helicobacter pylori infection Stomach surgery History of peptic ulcer and gastrointestinal malignancies Having any disease that causes inflammation and increased levels of inflammatory markers, such as diabetes, cardiovascular disease, respiratory infections such as asthma and ... Getting immunodeficiency diseases Developing chronic diseases requiring drug treatment Taking medications other than prescription drugs Receiving antibiotics or proton pump inhibitors or H2 blockers over the past 2 months Taking omega supplementation At least 3 months before the start of the study Use of any diet supplements During the study 3 months before the start of the study Changes in the diet during the study period Consumption of less than 80% of the supplements delivered to the patient during the study period.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
By using randomized blocked categorization (4 block based on BMI and sex), individuals will be placed in one of the three intervention groups or in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Jundishapur University of Medical Sciences
Street address
Golestan Highway, Jundishapur University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715751
Approval date
2018-01-05, 1396/10/15
Ethics committee reference number
IR.AJUMS.REC.1396.819

Health conditions studied

1

Description of health condition studied
Helicobacter pylori
ICD-10 code
B98.0
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Negative cases of Helicobacter pylori infection
Timepoint
Three weeks after the end of treatment
Method of measurement
Checking of H.Pylori stool antigen

2

Description
Scale of gastrointestinal complaints questionnaire from Helicobacter pylori infection
Timepoint
Before and at the end of the study
Method of measurement
Questionnaire

3

Description
Serum levels of Il-17, TGFβ1 and INF-γ
Timepoint
Before and at the end of the study
Method of measurement
ELISA method

4

Description
Serum levels of TAC and MDA
Timepoint
Before and after study
Method of measurement
ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Two weeks of helicobacter pylori triple therapy, including daily intake of pantoprazole 80 mg , amoxicillin 2 g, bismuth 8 mg and clarithromycin 1 g + cranberry juice (400 ml)) Enriched with omega 3 (two grams)
Category
Treatment - Other

2

Description
Intervention group: Two weeks of helicobacter pylori triple therapy, including daily intake of pantoprazole 80 mg , amoxicillin 2 g, bismuth 8 mg and clarithromycin 1 g + cranberry juice (400 ml))
Category
Treatment - Other

3

Description
Intervention group: Two weeks of helicobacter pylori triple therapy, including daily intake of pantoprazole 80 mg , amoxicillin 2 g, bismuth 8 mg and clarithromycin 1 g + omega-3 (two grams)
Category
Treatment - Other

4

Description
Control group: Two weeks of helicobacter pylori triple therapy, including including daily intake of pantoprazole 80 mg , amoxicillin 2 g, bismuth 8 mg and clarithromycin 1 g
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Soroush Clinic
Full name of responsible person
Dr. Pezhman Alavinezhad
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Kianpars st., Western Vahabi st., Soroush st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
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
Ahvaz University of Medical Sciences
Full name of responsible person
Leila Maghsoumi-Nourozabad
Position
Nutrition PhD student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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