

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 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 between 18 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 Pantoprazole 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 Pantoprazole 80 mg , Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g and Cranberry juice (400 ml) for 4 weeks Group 3: Two weeks taking Pantoprazole 80 mg , Amoxicillin 2 g, Bismuth 8 mg, Clarithromycin 1g and omega 3 (two grams) for 4 weeks Control group: Two weeks taking Pantoprazole 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)

Phone

+98 61 3373 8319

Email address

zarejavid-a@ajums.ac.ir

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.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

No information

Sample sizeTarget 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

Khuzestan

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

Street address

Kianpars st., Western Vahabi st., Soroush st.

City

Ahvaz

Province

Khouzestan

Postal code

6135715751

Phone

+98 61 1373 8330

Email

ahmaddjavid@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Golestan Highway;Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

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

Street addressGolestan Highway, faculty of paramedicine,
Department of nutrition, Jundishapur University of
Medical Sciences**City**

Ahvaz

Province

Khouzestan

Postal code

6135715751

Phone

+98 61 3373 8330

Email

l.maghsoumi55@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Ahmad Zare Javid

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street addressGolestan Highway, Faculty of Paramedicine,
Department of Nutrition, Jundishapur University of
Medical Sciences**City**

Ahvaz

Province

Khouzestan

Postal code

6135715751

Phone

+98 61 3373 8330

Email

ahmaddjavid@gmail.com

Person responsible for updating data**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

Street addressGolestan Highway, faculty of paramedicine,
Department of nutrition, Jundishapur University of
Medical Sciences**City**

Ahvaz

Province

Khouzestan

Postal code

6135715751

Phone

+98 61 3373 8330

Email

l.maghsoumi55@gmail.com

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