# 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**
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Ahvaz University of Medical Sciences
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Dr. Mohammad Badavi
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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
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Leila Maghsoumi-Nourozabad
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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