

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of therapeutic effectiveness of Probiotic on eradication of Helicobacter Pylori infection in Adults

#### Protocol summary

##### Summary

The study groups are probiotic and control ( 60 patients in each group) with confirmed H. Pylori infection by either fecal H.Pylori antigen or Urea Breath Test . Both groups will receive a 10-day standard H.Pylori eradication regimen ( Amoxicillin and Clarithromycin and Omeprazol) ; but the probiotic preparation would be introduced for probiotic group. 4 weeks after finishing of treatment, the eradication will be confirmed by either fecal H.Pylori antigen or Urea Breath Test. The rate of eradication and patient's compliance and side effects will be compared between two study groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071523219N1**  
Registration date: **2015-10-21, 1394/07/29**  
Registration timing: **prospective**

Last update:  
Update count: **0**

##### Registration date

2015-10-21, 1394/07/29

##### Registrant information

###### Name

Hadi Karimzadeh

###### Name of organization / entity

Zahedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5770

###### Email address

karimzadeh@zaums.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Zahedan University of Medical Sciences

##### Expected recruitment start date

2015-10-22, 1394/07/30

##### Expected recruitment end date

2016-08-20, 1395/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effectiveness of Probiotic on eradication of Helicobacter Pylori infection in Adults

##### Public title

Therapeutic effectiveness of Probiotic in GI Infection

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: Age >18 Years; Dyspepsia; confirmed H.Pylori Exclusion criteria : acute and chronic GI disease; Renal failure; Neurological disease; use of Antibiotic or probiotic within previous 30 days

##### Age

From **18 years** old to **80 years** old

##### Gender

Both

##### Phase

2-3

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **120**

##### Randomization (investigator's opinion)

Randomized

#### Randomization description

**Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Zahedan University of Medical Sciences

**Street address**

University Campus, Hesabi Square,

**City**

Zahedan

**Postal code****Approval date**

2015-06-28, 1394/04/07

**Ethics committee reference number**

IR.Zaums.Re.1394.145

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

Helicobacter pylori Infection

**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**

H.pylori Infection

**Timepoint**

Before and 4 weeks after end of treatment

**Method of measurement**

Fecal H.pylori or Urea Breathing Test

**Secondary outcomes****1****Description**

Allergia; Diarrhea; Nausea; Vomiting; Bloating

**Timepoint**

Before and 4 weeks after end of treatment

**Method of measurement**

Hystory and Physical exam

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

B group : cap placebo/ 1 cap / q 12 h and standard regimen for H. pylori eradication

**Category**

Placebo

**2****Description**

A group: cap Familact / 1 cap/ q 12 h and standard regimen for H. pylori eradication

**Category**

Treatment - Drugs

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

Ali-Ebne-Abitaleb Hospital

**Full name of responsible person****Street address**

Department of Internal Medicine, Ali-Ebne-Abitaleb Hospital

**City**

Zahedan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hadi Karimzadeh, M.D

**Street address**

Department of Internal Medicine, Ali-Ebne-Abitaleb Hospital

**City**

Zahedan

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

Yes

**Title of funding source**

Zahedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

*empty*

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

*empty*

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

Zahedan University of Medical Sciences

**Full name of responsible person**

Alireza Bakhshipour, M.D

**Position**

Gastroenterologist

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

Hadi Karimzadeh, M.D

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Alireza Bakhshipour, M.D

**Position**

Gastroenterologist

**Other areas of specialty/work****Street address**

Department of Internal Medicine, Ali-Ebne-Abitaleb  
Hospital

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*