Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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; Diarrea; Nausea; Vometing; 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
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Department of Internal Medicine, Ali-Ebne-Abitaleb Hospital
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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
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

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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