Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison between the probiotic supplementation and the placebo on the tolerance and efficacy of quadruple therapy in helicobacter pylori positive patients

Protocol summary

Summary

This is a randomized double blind placebo controlled trial on 80 h.pylori positive patients diagnosed by histopathology, in Rasht and Anzali, Iran, in one year period in 2011-2012. The inclusion criterion is the presence of h.pylori by histopathology of the biopsy specimen. The exclusion criteria are malignancy; prior h.pylori eradication; GI bleeding; prior gastrectomy; inflammatory bowel disease; immunodeficiency; valvular heart disease; any probiotic supplementation consumption in treatment period. The patients are divided in the placebo and the treatment group by random allocation. The treatment group receives quadruple therapy of Clarithromycin 500 mg bid, Amoxicillin 1g bid, Bismuth 525mg qid, Omeprazole 20 mg bid and 2 probiotic capsules(Protexin BALANCE) daily for 14 days. The placebo group also receives the same quadruple therapy and 2 Placebo capsules daily for 14 days. Meanwhile, receiving of the placebo and the probiotic capsule in the placebo and the treatment group begins 3 days before the starting of 14 days therapy, respectively. The assessment of symptoms improvement and the drug adverse effects is done by Glasgow dyspepsia questionnaire and modified version of the questionnaire by de Boer et al. The h.pylori eradication is confirmed by urea breath test(UBT) 4 weeks after the finishing of treatment period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011135174N1**
Registration date: **2011-05-10, 1390/02/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-10, 1390/02/20

Registrant information

Name
Afshin Shafaghi
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 13 1555 4593
Email address
ashafaghi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dean of Medical School, Guilan University of Medical Sciences

Expected recruitment start date

2011-05-05, 1390/02/15

Expected recruitment end date

2012-04-03, 1391/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the probiotic supplementation and the placebo on the tolerance and efficacy of quadruple therapy in helicobacter pylori positive patients

Public title

The effect of probiotics in the treatment of H.pylori

infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: diagnosed h.pylori infection by histopathology of the biopsy specimen. Exclusion criteria: malignancy; prior h.pylori eradication; GI bleeding; prior gastrectomy; inflammatory bowel disease; immunodeficiency; valvular heart disease; consuming any probiotic supplementation in treatment period.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethics Committee of Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, in front of Alzahra hospital, Shahid Saadati street, Namju street, Rasht

City

Rasht

Postal code

4144668164

Approval date

2011-01-29, 1389/11/09

Ethics committee reference number

12414

Health conditions studied

1

Description of health condition studied

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Indigestion

2

Description of health condition studied

Gastric ulcer

ICD-10 code

K25

ICD-10 code description

erosion (acute) of stomach, ulcer (peptic): pylorus,stomach

3

Description of health condition studied

Duodenal ulcer

ICD-10 code

K26

ICD-10 code description

erosion (acute) of duodenum, ulcer (peptic): duodenal-postpyloric

Primary outcomes

1

Description

H.pylori eradication rate

Timepoint

6 weeks and 3 days after the beginning of the intervention

Method of measurement

Urea breath test

2

Description

Diarrhea

Timepoint

10, 17 and 24 days after the beginning of the intervention

Method of measurement

Modified version of the questionnaire by de Boer et al

3

Description

Epigastric pain

Timepoint

10, 17 and 24 days after the beginning of the intervention

Method of measurement

Modified version of the questionnaire by de Boer et al

4

Description
Nausea
Timepoint
10, 17 and 24 days after the beginning of the intervention
Method of measurement
Modified version of the questionnaire by de Boer et al

5

Description
Flatulence
Timepoint
10, 17 and 24 days after the beginning of the intervention
Method of measurement
Modified version of the questionnaire by de Boer et al

6

Description
Taste disorder
Timepoint
10, 17 and 24 days after the beginning of the intervention
Method of measurement
Modified version of the questionnaire by de Boer et al

7

Description
Constipation
Timepoint
10, 17 and 24 days after the beginning of the intervention
Method of measurement
Modified version of the questionnaire by de Boer et al

Secondary outcomes

1

Description
Benign peptic ulcer
Timepoint
At the begining of the trial
Method of measurement
Gastroduodenoscopy

2

Description
Duodenal ulcer
Timepoint
At the begining of the trial
Method of measurement
Gastroduodenoscopy

3

Description
Nonulcer dyspepsia
Timepoint
At the begining of the trial
Method of measurement
Gastroduodenoscopy

Intervention groups

1

Description
The intervention group: probiotic Protexin BALANCE, 2 Capsules, daily, 17 days
Category
Treatment - Drugs

2

Description
The control group: Placebo, 2 capsules, daily, 17days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Mr. Afshin Shafaghi
Street address
City
Rasht

2

Recruitment center
Name of recruitment center
Private clinic in Anzali
Full name of responsible person
Mr. Afshin Shafaghi
Street address
City
Anzali

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dean of Medical School, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abtin Heidarzadeh
Street address
School of Medicine, The University of Guilan, Rasht
City
Rasht
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dean of Medical School, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Dr. Afshin Shafaghi

Position

Gastroenterologist

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

Guilan Univercity of Medical Sciences

Full name of responsible person

Mohsen Khosravani

Position

Medical student

Other areas of specialty/work

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Web page address

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