

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of Helicobacter pylori eradication on symptom improvement in patients with abdominal bloating

Protocol summary

Summary

The aim of study is to investigate the effect of Helicobacter pylori eradication on abdominal bloating symptom improvement. Patients will be selected based on a questionnaire completed by direct interview in internal medicine clinic of Imam Khomeini Hospital and Special University Clinic No 2. Patients will be randomized in two groups; treatment and placebo. Inclusion criteria: having abdominal bloating symptom during at list 3 months with at least 2 points severity; a positive H.pylori ELISA serologic test. Exclusion criteria: History of gastrointestinal bleeding; any evidence of malignancy; If any evidence of epigastric pain or burning sensation bye eating; If there is bloating or diarrhea which was triggered with dairy product or gluten containing foods; malabsorption evidences; Bloody diarrhea or fresh rectal bleeding without symptoms only suggestive of hemorrhoid or fissure; Abdominal pain referred to the back or sever positional pain; Previous history of gastrointestinal surgery or resection; Failure to complete treatment period of at least 80%; patient's unwillingness to continue treatment. Also drugs which may cause bias on the study would be discontinued one week before starting trial. The symptom score would be documented at the beginning of the study(with 5-point Likert system), 2 weeks, 4 and 6 weeks after treatment . Eradication protocol consists of two weeks treatment with omeprazole, metronidazole, amoxicillin, and bismuth subcitrate. At the end of the treatment, the patients come back to do Urease Breath Test (UBT) for evaluation of helicobacter pylori eradication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012112711592N1**

Registration date: **2013-06-29, 1392/04/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-29, 1392/04/08

Registrant information

Name

Bitra Anvari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3727 8759

Email address

banvari88@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science-Imam Khomeini Hospital

Expected recruitment start date

2013-06-25, 1392/04/04

Expected recruitment end date

2014-02-21, 1392/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Helicobacter pylori eradication on symptom improvement in patients with abdominal bloating

Public title

Effect of Helicobacter pylori eradication on symptom improvement in patients with abdominal bloating

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having abdominal bloating symptom during at list 3 months with at least 2 points severity; a positive H.pylory ELISA serologic test. Only patients with score 2 or greater would be included in trial. Exclusion criteria: History of gastrointestinal bleeding; any evidence of malignancy; If any evidence of epigastric pain or burning sensation bye eating; If there is bloating or diarrhea which was triggered with dairy product or gluten containing foods;malabsorption evidences; Bloody diarrhea or fresh rectal bleeding without symptoms only suggestive of hemorrhoid or fissure; Abdominal pain referred to the back or sever positional pain; Previous history of gastrointestinal surgery or resection; Failure to complete treatment period of at least 80%; patient's unwillingness to continue treatment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Kermanshah University of
Medical Science

Street address

Medical Science university_Shahid Beheshti
blvd_Kermanshah

City

Kermanshah

Postal code

10536

Approval date

2013-03-04, 1391/12/14

Ethics committee reference number

7/420/540/ت

Health conditions studied

1

Description of health condition studied

abdominal bloating

ICD-10 code

k63.9

ICD-10 code description

Disease of intestine, unspecified

2

Description of health condition studied

abdominal bloating

ICD-10 code

k92.8

ICD-10 code description

Other specified diseases of digestive system

Primary outcomes

1

Description

abdominal bloating improvement

Timepoint

just before starting treatment, 2 weeks, 4 and 6 weeks
after it

Method of measurement

5 point likert score

Secondary outcomes

empty

Intervention groups

1

Description

group B: 2 weeks placebo

Category

Treatment - Drugs

2

Description

group A: two weeks treatment with omeprazole 20 mg
twice daily, metronidazole 500 mg twice daily,
amoxicillin 1000 mg twice daily, and bismuth subcitrate
240 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

clinic of internal medicine, imam khomeini hoapital

Full name of responsible person

bita anvari

Street address

naghlieh bolv

City

kermanshah

2**Recruitment center****Name of recruitment center**

NO.2 Clinic of kermashah university of medical science

Full name of responsible person

bita anvari

Street address

kasra street

City

kermanshah

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

Ketmanshah University of Medical Science

Full name of responsible person

Farid Najafi

Street address

Building No.2, Shahid Beheshti Bolv. Ketmanshah,Iran

City

Kermanshah

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

Yes

Title of funding source

Ketmanshah University of Medical Science

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**

Kermanshah University of Medical Science

Full name of responsible person

Bita Anvari

Position

Internist

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

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10536

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Fax**Email**

drs.setareh@gmail.com

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