Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Bita 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 ofMedical Science
Full name of responsible person
Bita Anvari
Position
Internist
Other areas of specialty/work
Street address
Naghlieh bolv.-Imam Khomeini Hospital
City
Kermanshah
Postal code
6714869914
Phone
+98 83 1727 8759
Fax
+98 42 76477
Email
banvari88@kums.ac.ir
Web page address

Person responsible for scientific 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
Naghlieh bolv.- Imam Khomeini Hospital
City
Kermanshah
Postal code
6714869914
Phone
+98 83 1727 8759
Fax
+98 42 76477
Email
banvari88@kums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah Universitiy of Medical Science
Full name of responsible person
Setareh Naderi
Position
Intern
Other areas of specialty/work
Street address
Number3-Sharghi 3 alley- Twenty meters east of St-Dadgostary Town
City
Kermanshah
Postal code
10536
Phone
+98 83 1826 7003
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