

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of helicobacter pylori eradication on iron stores in patients with dyspepsia

Protocol summary

Summary

The aim of the study and study design: During this study we will use three treatment protocols for eradication of H pylori and we will compare the effectiveness of each protocol on iron reserve. The study is a randomized controlled trial. Study population contains patients with dyspepsia and H Pylori infection with low iron reserves who referred to GI clinic of Ali Ibn Abitalib Hospital of Zahedan during 2016. Inclusion criteria: patients with dyspepsia symptoms who their H pylori infection was proven by endoscopy and biopsy; ferritin serum level less than 40 ng /ml; negative CRP test. Exclusion criteria: History of treatment of helicobacter pylori during last 6 months; history of iron supplement intake among last 6 months; known underlying diseases associated with iron deficiency; lack of informed consent. Sample size: 108 Random allocation will apply by balanced block randomization to selection tree groups. • Control Group: H.Pylori eradication alone for 2 weeks. Drugs for eradication are: furazolidone 200mg/BD, omeprazole 20mg/BD, bismut 240mg/BD, Amoxicillin 1gr/BD. • Intervention Group 1: H.pylori eradication for 2 weeks and simultaneously start of iron complement for 8 weeks. • Intervention Group 2: H.pylori eradication for 2 weeks and after ccompleting the eradication, iron complement is used for 8 weeks. Drugs for eradication are : furazolidone 200mg/BD, omeprazole 20mg/BD, bismut 240mg/BD, Amoxicillin 1gr/BD. Iron Complement : ferrous sulfate 300mg/TDS Project duration: 12 months Outcome: improve iron status after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021626593N1**

Registration date: **2016-10-26, 1395/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-26, 1395/08/05

Registrant information

Name

Farhad Yarmohammadi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3348 6260

Email address

frdflower@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of helicobacter pylori eradication on iron stores in patients with dyspepsia

Public title

Effect of gastrointestinal infection eradication on iron stores

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with dyspepsia symptoms who their H pylori infection was proven by endoscopy and biopsy; ferritin serum level less than 40 ng /ml; negative CRP test. Exclusion criteria: History of treatment of helicobacter pylori during last 6 months; history of iron supplement intake among last 6 months; known underlying diseases associated with iron deficiency; lack of informed consent.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not 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

Zahedan, Daneshgah Street, Dr.Hesabi Square, Pardis of Medical University

City

Zahedan

Postal code

Approval date

2015-12-16, 1394/09/25

Ethics committee reference number

IR.ZUMS.REC.1394.374

Health conditions studied

1

Description of health condition studied

Helicobacter Pylori Infection

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

2

Description of health condition studied

Iron Deficiency

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anemia, unspecified

Primary outcomes

1

Description

Hemoglobin

Timepoint

Before Intervention

Method of measurement

Sysmex K21

2

Description

CRP

Timepoint

Before Intervention

Method of measurement

Latex Agglutination

3

Description

Ferritin

Timepoint

Before and After Intervention

Method of measurement

Eliza Method

Secondary outcomes

1

Description

Ferritin

Timepoint

After Intervention

Method of measurement

Eliza Method

2

Description

Helicobacter Pylori Fecal Antigen

Timepoint

After Intervention

Method of measurement

Stool Examination

Intervention groups

1

Description

Intervention Group : 1- First Group : H.pylori eradication for 2 weeks and simultaneously use of iron complement for 8 weeks. 2- Second Group : H.pylori eradication for 2 weeks and when eradication approved iron complement be used for 8 weeks. Drugs for eradication are : furazolidone 200mg/BD, omeprazole 20mg/BD, bismut 240mg/BD, Amoxicillin 1gr/BD. Iron Complement : ferrous sulfate 300mg/TDS

Category

Treatment - Drugs

2

Description

Control Group : H.Pylori eradication alone for 2 weeks. Drugs for eradication are : furazolidone 200mg/BD, omeprazole 20mg/BD, bismut 240mg/BD, Amoxicillin 1gr/BD.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences, Ali Ibn Abitalib Hospital

Full name of responsible person

farhad yarmohammadi

Street address

Zahedan, Daneshgah Street, Dr.Hesabi Square, Pardis of Medical University

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

farhad yarmohammadi

Street address

Zahedan, Daneshgah Street, Dr.Hesabi Square, Pardis of Medical University

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

farhad yarmohammadi

Position

Internal medicine resident, executor of plan

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

farhad yarmohammadi

Position

Internal medicine resident

Other areas of specialty/work

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Contact

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Full name of responsible person

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Position

Internal medicine resident

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

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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