

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Beneficial effects of helicobacter pylori eradication on severity and frequency of migraine headache

Protocol summary

Summary

With very high prevalence of *Helicobacter pylori* infection in developing countries and the high prevalence of headaches migraine aim of this study is whether *Helicobacter pylori* is a risk factor for migraine? Does treatment and eradication of *Helicobacter pylori* can reduce the number of migraine attacks and can be approved as a therapeutic approach to be used in patients with migraine? The overall objective of the study: The treatment of *Helicobacter pylori* infection in the reduction severity and number of monthly attacks, migraine headaches. Application of research results: *Helicobacter pylori* testing in patients with migraine and eradication in the presence of infection will help treat migraine attacks in these individuals. Neurology outpatient clinic and patients referred to the Farshchian health center neurology clinic with headache were evaluated in terms of Migraine and If meet the International Headache Society criteria for migraine were diagnosed after obtaining the consent, are enrolled and placed under serological test for *H. pylori* Ig G a non-invasive test, sensitive and specific for detection of *Helicobacter pylori*. In the case of a positive test results patients entered using the form collects information about age and sex and Headache characteristics, including: the severity of headache attacks (Based on the numbers 1_10), the average monthly number of attacks (Based on the number of attacks per month), Intensify with menstrual(y or n), family history of headache(y or n) get Information. All patients underwent standard four-drug therapy *Helicobacter pylori* with Omeprazol 20 mg Bid, Bismuth 240 mg Bid, Tetracyclin 500 mg Qid, and Metronidazol 500 mg Bid for four weeks. After 4 weeks of the end of treatment urea breath test to confirm eradication and headache characteristics are investigated. The main outcome variables are: the number of migraine attacks and severity of migraine attacks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202018896N1**

Registration date: **2012-05-02, 1391/02/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-02, 1391/02/13

Registrant information

Name

Niloufar Hemmati

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1823 2771

Email address

shakhenabat1979@yahoo.com

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-01-05, 1390/10/15

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Beneficial effects of helicobacter pylori eradication on severity and frequency of migrane headache

Public title

Beneficial effects of helicobacter pylori eradication on severity and frequency of migrane headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All people with headaches meet the International Headache Society criteria (moderate to severe headache, unilateral, pulsatile; intensified with routine activities with nausea and vomiting associated with photophobia and multiple attacks during 72-4 h).
Exclusion criteria: lack of patient satisfaction; identify other causes of headache during treatment and previous treatment of Helicobacter pylori

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences Ethics Committee

Street address

Fahmideh .ave

City

Hamedan

Postal code

Approval date

2012-01-05, 1390/10/15

Ethics committee reference number

3586|9|35|16|پ

Health conditions studied

1

Description of health condition studied

Migrane

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

The number of migraine attacks

Timepoint

Before and after the standard treatment for H. pylori infection

Method of measurement

the average monthly number of headache attacks (based on number of attacks per month

2

Description

Severity of migraine attacks

Timepoint

Before and after the standard treatment for H. pylori infection

Method of measurement

The severity of headache attacks (on the basis of numbers 10_1)

Secondary outcomes

1

Description

Eradication rate of Helicobacter pylori infection
[Helicobacter pylori infection in patients with migraine

Timepoint

After treatment

Method of measurement

Urea breath test to confirm eradication

Intervention groups

1

Description

Standard four-drug protocol for H. pylori eradication was employed with Omeprazol 20 mg Bid, Bismuth 240 mg Bid, Tetracyclin 500 mg Qid, and Metronidazol 500 mg Bid for four weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical center and outpatient neurology clinic of
Hamadan Farshchian

Full name of responsible person

Dr. Mazaheri

Street address

Mirzadeh Eshghi ave.

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research of Hamedan University of
Medical Sciences

Full name of responsible person

Dr Ali Ghaleiha

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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

Vice-chancellor for research of Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Niloufar Hhemmati

Position

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Dr. Amir Majlesi

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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