Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

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Name of organization / entity
Hamedan University of Medical Sciences
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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 Ghaleiiha
Street address
Fahmideh .ave
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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
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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