Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Helicobacter Pylori eradication on reducing the frequency, intensity and duration of headache attacks in migraine patients without aura

Protocol summary

Study aim
The effect of Helicobacter Pylori eradication in improving the symptoms of migraine patients

Design
Before and after clinical trial without control group and without blinding, phase 2 on 35 patients

Settings and conduct
Patients with migraine without aura were diagnosed by a neurologist at the Ghaem Mashhad Hospital based on the IHS criteria. At the beginning of the study, migraine attacks are evaluated using the MIDAS questionnaire, and patients with a MIDAS score greater than 6 are referred to a gastroenterologist. Then, people with a positive Helicobacter Pylori fecal antigen test are included in the study. In addition to classic migraine treatment, all patients will receive a Helicobacter Pylori eradication regimen (3-drug regimen with amoxicillin 1000 mg every 12 hours, clarithromycin 500 mg every 12 hours, and omeprazole 20 mg every 12 hours for 2 weeks). After 4 weeks from the end of the treatment, fecal antigen tests are performed again in order to check the eradication of Helicobacter. Re-evaluation in terms of the number and severity of migraine attacks is done 3 months after the end of the treatment. Patients will receive medical treatment with sumatriptan 50 mg tablets in case of an acute migraine attack.

Participants/Inclusion and exclusion criteria
Patients with migraine without aura were diagnosed by a neurologist based on the criteria of the International Headache Society (IHS) over 16 years old, suffering from migraine without aura, a positive Helicobacter pylori fecal antigen test and the ability of cooperation

Intervention groups
A Helicobacter Pylori eradication regimen will be given to the intervention group for 2 weeks

Main outcome variables
Assessment of migraine severity based on a questionnaire before and after Helicobacter Pylori treatment, assessment of the prevalence of Helicobacter Pylori in migraine patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241011063326N1**
Registration date: **2024-10-31, 1403/08/10**
Registration timing: **prospective**

Last update: **2024-10-31, 1403/08/10**
Update count: **0**

Registration date
2024-10-31, 1403/08/10

Registrant information

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Hossein Alimardani
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-05, 1403/08/15

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Helicobacter Pylori eradication on reducing the frequency, intensity and duration of headache attacks in migraine patients without aura

Public title
The Effect of Helicobacter Pylori Eradication on Migraine
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Migraine without aura according to IHS diagnostic criteria Helicobacter Pylori fecal antigen positive test Lack of control of migraine attacks despite the classic treatment of migraine (the MIDAS score is mostly equal to 6, which is performed by a neurologist)
Exclusion criteria:
Inability to cooperate Consumption of alcohol, smoking and contraceptive drugs Pregnancy
Age
From **16 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **35**
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
Ethics committee of Mashhad University of Medical Sciences
Street address
No.15 , Majd 10 Ave., Majd Blvd., Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9184877370
Approval date
2024-03-03, 1402/12/13
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.510

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Severity score of migraine attacks in MIDAS questionnaire
Timepoint
The beginning of the study (before the start of the intervention), 3 months after completing the Helicobacter Pylori eradication regimen
Method of measurement
Migraine disability assessment questionnaire

Secondary outcomes

1

Description
The prevalence of Helicobacter Pylori in patients with migraine without aura
Timepoint
The beginning of the study (before the start of the intervention)
Method of measurement
Helicobacter Pylori fecal antigen test

2

Description
Eradication rate of Helicobacter Pylori in patients with migraine without aura after completion of treatment
Timepoint
4 weeks after the completion of the Helicobacter Pylori eradication regimen
Method of measurement
Helicobacter Pylori fecal antigen test

Intervention groups

1

Description
Intervention group: Helicobacter Pylori eradication regimen (3-drug regimen) with amoxicillin 1000 mg every 12 hours, clarithromycin 500 mg every 12 hours, and omeprazole 20 mg every 12 hours for 2 weeks will be given to all patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Ghaem Hospital
Full name of responsible person
Mohammad shariati
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Research assistant of Mashhad University of Medical Sciences
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University Ave., in front of University 18, building number one of Mashhad University of Medical Sciences (Qureshi), second floor, Research and Technology Vice-Chancellor
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sram@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Hossein Alimardani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available