Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of additional treatment of Helicobacter Pylori infection on the severity of headaches in patients with idiopathic headache

Protocol summary

Summary

Headache is one of the most common diseases that people can get it in their life-long. Recently there are evidences indicating the role of H. Pylori as a cause of headache. The aim of our study is to investigate the effects of simultaneous treatment of Helicobacter Pylori on reducing symptoms of patients with idiopathic headache. In this double-blind case-control study, 210 patients with idiopathic headache and simultaneous symptoms of dyspepsia were divided randomly into two groups after considering the inclusion and exclusion criteria of the study and with no gender preference. MIDAS questionnaire was completed for both groups to determine the severity of headache and case group received two weeks treatment of Helicobacter Pylori in addition to one month treatment of headache and after one-month treatment period of headache, MIDAS questionnaire was completed again for both groups. Then MIDAS score was compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109046056N3**
Registration date: **2011-09-14, 1390/06/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-09-14, 1390/06/23

Registrant information

Name

Nader Zarinfar

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Research Council

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-09-22, 1390/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of additional treatment of Helicobacter Pylori infection on the severity of headaches in patients with idiopathic headache

Public title

Additional treatment of Helicobacter Pylori infection on the severity of headaches in patients with idiopathic headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Ideoathic headache 2- Age over 20 years old 3- Dyspepsia 4- IgG against H.pylori over 30u/m Exclusion criteria: 1- Classic treatment for H.pylori in 6-3 months ago 2- Uses of β-blockers or calcium channel blockers in last month 3- Uses of antipsycotic drugs in last month 4- Uses of antiepilepthic drugs in last month 5- Pregnancy 6- Have controindication to

antibiotic against H.pylori 7- Disinclination to continue the study

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **210**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of Medical Sciences

Street address
Arak, Alamalhoda ave, Arak University of Medical Sciences

City
Arak

Postal code

Approval date
2010-10-06, 1389/07/14

Ethics committee reference number
89-94-1

Health conditions studied

1

Description of health condition studied
Migraine without aura

ICD-10 code
G43.0

ICD-10 code description
Migraine: . aura without headache · basilar· equivalents familial hemiplegic · with: acute-onset aura · prolonged aura · typical aura

Primary outcomes

1

Description
Clinical improvement and result of serologic test

Timepoint
In beginning of the study and the end of month one clinical evaluation

Method of measurement
Patient history and physical exam and MIDAS questionare

Secondary outcomes

1

Description
Failure to treatment

Timepoint
End of treatment

Method of measurement
Clinical AND Serological evaluation

2

Description
Drug side effects

Timepoint
During treatment

Method of measurement
Clinical evaluation

Intervention groups

1

Description
In a case group: Patient received Nortriptyline 10 mg nightly and Sodium valproate 200 mg daily and for dispepsia received omeprazole 20 mg and Bismuth Subcitrate 120mg twice daily, Metronidazole 250mg three times a day and Tetracycline 250mg four times a day.

Category
Treatment - Drugs

2

Description
Control group received Nortriptyline 10 mg nightly and Sodium valproate 200 mg daily

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valie-Asr Hospital

Full name of responsible person
Dr nader zarinfar,Assistant professor Arak University of Medical Sciences, Infectious disease specia
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Valie-Asr Hospital , Pirozi Ave, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr.Davoud Hekmatpour
Street address
Arak University of Medical Sciences , Basij square,Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
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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