

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 86 1224 1411

Email address

zarinfar@arakmu.ac.ir

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- Ideopathic 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 antipsychotic drugs in last month 4- Uses of antiepileptic drugs in last month 5- Pregnancy 6- Have contraindication 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· equivalentents
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

Street address

Valie-Asr Hospital , Pirozi Ave, Arak

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Nader Zarinfar

Position

Assistant professor,Infectious disease specialist

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

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Dr Nader Zarinfar

Position

Assistant professor, Infectious disease specialist

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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****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Nader Zarinfar

Position

Infectious disease specialist

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

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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