

# 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  $\beta$ -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 questionnaire

## 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 dyspepsia 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

**City**

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**Email**

zarinfar@arakmu.ac.ir

**Web page address**

portal.arakmu.ac.ir

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

Arak University of Medical Sciences

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Dr Nader Zarinfar

**Position**

Assistant professor, Infectious disease specialist

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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*