

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The efficacy of nonsteroidal anti-inflammatory drugs (NSAIDs) in shortening the Helicobacter pylori eradication period

#### Protocol summary

##### Summary

Helicobacter pylori (H. pylori) colonizes not only on the surface of mucous membrane but also beneath the surface mucous gel layer (SMGL). As Na-diclofenac decreases the secretion of SMGL, in this study we examined this drug as an adjuvant therapy to a quadruple therapy for H. Pylori eradication. One hundred and seventy-two patients were randomly assigned to three groups. Fifty four patients received azithromycine 250 mg ,amoxicillin 500 mg, bismuth subcitrate 240 mg and omeprazole 20 mg) twice a day for 1 week (group A) and 65 patients received the same dosage of those agents plus Na -diclofenac tab, 100 mg daily for 1 week (group B). Sixty two patients received the same quadruple therapy for 2 weeks (group C), Eradication of the infection will assess four to six weeks after completion of treatment by stool antigen assay for H. pylori and finally 8-10 weeks after treatment symptoms improvement will evaluate by glasgow dyspepsia severity questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204059256N2**

Registration date: **2012-05-13, 1391/02/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-05-13, 1391/02/24

##### Registrant information

##### Name

Ali Toghiani

##### Name of organization / entity

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##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2010-04-01, 1389/01/12

##### Expected recruitment end date

2011-04-01, 1390/01/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of nonsteroidal anti-inflammatory drugs (NSAIDs) in shortening the Helicobacter pylori eradication period

##### Public title

Effect of NSAIDs in H.pylori treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: patients with H.pylori infection.

Exclusion criteria: previous treatment for H. pylori infection; use of PPI (proton pump inhibitors) during 2 weeks and/or antibiotics during 4 weeks before the study; having peptic ulcer, GERD, gastrointestinal malignancy, previous gastro-oesophageal surgery; severe concomitant cardiovascular, hypertension,

respiratory or endocrine diseases, clinically significant renal or hepatic disease, haematological disorders; any other clinically significant medical conditions that could increase risk; history of allergy to any of the drug used in the study; pregnancy or lactation; alcohol abuse; drug addiction; severe neurological or psychiatric disorders and contraindication of consumption of NSAID and long-term use of corticosteroids or anti-inflammatory drugs

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **172**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences Ethics Committee

**Street address**

Isfahan University of Medical Sciences, Isfahan, Iran.

**City**

Isfahan

**Postal code****Approval date**

2010-03-14, 1388/12/23

**Ethics committee reference number**

388565

**Health conditions studied****1****Description of health condition studied**

Helicobacter pylori

**ICD-10 code**

B98.0

**ICD-10 code description**

Helicobacter pylori [H.pylori] as the cause of diseases classified

**Primary outcomes****1****Description**

helicobacter pylori eradication

**Timepoint**

4-6 weeks after completion of treatment

**Method of measurement**

stool antigen assay for H. pylori.

**Secondary outcomes****1****Description**

symptoms improvement

**Timepoint**

8-10 weeks after treatment

**Method of measurement**

glasgow dyspepsia severity questionnaire

**Intervention groups****1****Description**

Fifty four patients received quadruple therapy i.e. azithromycine 250 mg, amoxicillin 500 mg, bismuth subcitrate 240 mg and omeprazole 20 mg bid for 1 week (group A)

**Category**

Treatment - Drugs

**2****Description**

Sixty five patients received quadruple therapy i.e. azithromycine 250 mg, amoxicillin 500 mg, bismuth subcitrate 240 mg and omeprazole 20 mg bid plus diclofenac Na tab, 100 mg daily for 1 week (group B).

**Category**

Treatment - Drugs

**3****Description**

Sixty two received quadruple therapy i.e. azithromycine 250 mg, amoxicillin 500 mg, bismuth subcitrate 240 mg and omeprazole 20 mg bid plus diclofenac Na tab, 100 mg daily for 2 weeks (group C)

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Al-zahra hospital

**Full name of responsible person**

**Street address**

**City**

Isfahan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research and technology

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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*