Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of nonsteroidal anti-inflammatory drugs (NSAIDs) in shortening the Helicobacterpylori 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 finaly 8-10 weeks after treatment symtoms improvement will evalute by glasgow dyspepsia severity questionnare.

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

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciencies

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 Helicobacterpylori 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 pomp 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, hypertention,

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
Isfahan University of Medical Sciences
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Person responsible for updating data

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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