Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Adding Ofloxacin to standard regimens versus standard triple-drug regimens consist of Clarithromycin, Amoxicillin, and Rabeprazole for Helicobacter Pylori Infection among patients with gastrointestinal problems based on Helicobacter pylori

Protocol summary

Summary

The aim of this study is comparing two Drugs regimen in order to eradication of H.pylori (Comparison standard 3-drugs regimen including Clarithromycin, Amoxicillin, and Rabeprazole with 3-drugs regimen plus Ofloxacin) among patients with gastrointestinal problems due to Helicobacter pylori that referred to the Ayatollah Rouhani Hospital of Babol university of Medical Sciences, 2015 Study design and population: 160 Patients were selected randomly allocated after endoscopy. The researcher does not know the type of drug so, this study is single blind. Inclusion criteria: positive biopsies for H. pylori; positive rapid urea's test for H. pylori, stomach ulcer; duodenal ulcer; dyspepsia with indications Helicobacter pylori eradication exclusion criteria: previous treatment for H. pylori; renal failure; receiving antibiotics during the last month; cirrhosis; pregnancy; breast feeding; gastric cancer. Intervention: In intervention group, standard regimen including Amoxicillin (1000 mg, Farabi company, Iran), Clarithromycin (500 mg, Farabi company, Iran), and Rabeprazole (20 mg, Farabi company, Iran), with adding ofloxacin (200 mg, twice a day Exir company, Iran), prescribed In control group, standard regimen including Amoxicillin (1000 mg, Farabi company, Iran), Clarithromycin (500 mg, Farabi company, Iran), and Rabeprazole (20 mg, Farabi company, Iran) prescribed twice daily up to 10 days In two group after 20 days, UBT (Urea's Breath Test) was performed in order to evaluate the efficacy of the protocol used in eradication of H. pylori. Primary outcome: eradication of Helicobacter pylori

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025292N1**
Registration date: **2016-02-09, 1394/11/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-09, 1394/11/20

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Adding Ofloxacin to standard regimens versus standard triple-drug regimens consist of Clarithromycin, Amoxicillin, and Rabeprazole for Helicobacter Pylori Infection among patients with gastrointestinal problems based on Helicobacter pylori

Public title
Efficacy of Ofloxacin in eradication of Helicobacter pylori
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: positive biopsies of H. pylori; positive rapid urease test of H. pylori, stomach ulcer; duodenal ulcer; dyspepsia with indications of Helicobacter pylori eradication. Exclusion criteria: previous treatment for H. pylori; renal failure; receiving antibiotics during the previous last month; cirrhosis; pregnancy; breast feeding; gastric cancer.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The researcher does not know the type of drugs so this study is single blind study. Patients were selected randomly allocated .

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol
City
Babol
Postal code
4717641367
Approval date
2014-10-12, 1393/07/20
Ethics committee reference number
MUBABOL.REC.1393.1

Health conditions studied

1

Description of health condition studied
Helicobacter Pylori Infection
ICD-10 code
B98.0
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
UBT (Urease Breath Test)
Timepoint
20 days after completing treatment
Method of measurement
Patients swallow urea labeled with an uncommon isotope, either radioactive carbon-14 or non-radioactive carbon-13. After10 to 30 minutes, the detection of isotope-labeled carbon dioxide in exhaled breath indicates that the urea was split.

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, standard regimen including Amoxicillin (1000 mg, Farabi company, Iran), Clarithromycin (500 mg, Farabi company, Iran), and Rabeprazole (20 mg, Farabi company, Iran), with adding ofloxacin (200 mg, twice a day Exir company, Iran), was prescribed
Category
Treatment - Drugs

2

Description
In control group, standard regimen including Amoxicillin (1000 mg, Farabi company, Iran), Clarithromycin (500 mg, Farabi company, Iran), and Rabeprazole (20 mg, Farabi company, Iran) were prescribed twice daily up to 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani Hospital of Babol
Full name of responsible person
Seyed Saeid Mohammadi Bonehi
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Rouhani Hospital, Ganjafroz Street, Babol
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Ali Bijani
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Babol University of Medical Sciences, Ganjafrooz street, Babol
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Babol 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

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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