Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of 5-day and 10-day levofloxacin-based concomitant regimen to eradication of Helicobacter pylori : A randomized clinical trial

Protocol summary

Study aim
Comparison of 5-day and 10-day levofloxacin based concomitant regimen to eradication of helicobacter pylori infection

Design
Randomized control trial, parallel group

Settings and conduct
this study is a randomised control trial conducted on patients of Ayatollah Rohani hospital, Babol, Iran who have proven H. pylori infection with histological sample. with respect to inclusion and exclusion criteria, Patients divided in two groups randomly and take levofloxacin based concomitant regimen for 5 or 10 days. Side effects of therapeutic regimen ask from patient during treatment period. H. pylori stool antigen test evaluated 6 weeks after the end of treatment.

Participants/Inclusion and exclusion criteria
inclusion criteria: All patients with the age of 18 to 80 years old with proven Helicobacter pylori infection with histological sample Exclusion criteria: chronic or severe disease, pregnant patients, taking antibiotics, NSAIDs or proton pump inhibitors over the last month, history of stomach surgery, severe impaired renal (Cr> 2 mg/dl) or hepatic function, gastric cancer, allergy to levofloxacin, amoxicillin, Metronidazole or pantoprazole

Intervention groups
Patients divided in two groups randomly group A: Amoxicillin 1 gr twice a day Levofloxacin 500 mg daily Metronidazole 500 mg twice a day Pantoprazole twice a day all regimen continue for 5 day group B: Amoxicillin 1 gr twice a day Levofloxacin 500 mg daily Metronidazole 500 mg twice a day Pantoprazole twice a day all regimen continue for 10 day

Main outcome variables
evaluation of the response of H.pylori infection treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190405043169N1**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

Registrant information

Name
Amin Vahedi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 4324 0633

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of 5-day and 10-day levofloxacin-based concomitant regimen to eradication of Helicobacter pylori : A randomized clinical trial

Public title
Comparison of two quadruple regimens to eradication of helicobacter pylori infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with the age of 18 to 80 years old with proven Helicobacter pylori infection with histological sample
Exclusion criteria:
age lesser than 18 years old or more than 80 years old taking antibiotics, NSAIDs or proton pump inhibitors over the last month history of stomach surgery severe impaired renal (Cr> 2 mg/dl) or hepatic function gastric cancer allergy to levofloxacin, amoxicillin, Metronidazole or pantoprazole pregnant patients chronic or severe disease
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are randomly divided by using a computer-generated random number list. The subjects are assigned into different groups by random allocation. Allocation concealment is obtained by maintaining the randomization list by study statistician.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

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, Ganjafrouz ave, Babol, Iran
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶۴۷۷۴۵
Approval date
2018-09-16, 1397/06/25
Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.182

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 to other chapters

Primary outcomes

1

Description
Rate of H pylori eradication
Timepoint
six weeks after the end of treatment
Method of measurement
H. pylori stool antigen test

Secondary outcomes

1

Description
side effects
Timepoint
six weeks after treatment
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: (N=60) this group take Amoxicillin 1 gr twice a day Levofloxacin 500 mg daily Metronidazole 500 mg twice a day Pantoprazole twice a day all regimen continue for 5 day
Category
Treatment - Drugs

2

Description
Control group: (N=60) this group take Amoxicillin 1 gr twice a day Levofloxacin 500 mg daily Metronidazole 500 mg twice a day Pantoprazole twice a day all regimen

continue for 10 day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani hospital, Babol

Full name of responsible person

javad shokri shirvani

Street address

Ayatollah Rohani hospital, Ganjafrouz ave, Babol, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

javad shokri shirvani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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medical student

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Medical doctor

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
اطلاعات مربوط به پیامد اصلی

When the data will become available and for how long
10 months after publication

To whom data/document is available
For people working in academic institutions

Under which criteria data/document could be used
No criteria

From where data/document is obtainable
aminvahedi@hotmail.com amin vahedi

What processes are involved for a request to access data/document
At least 2 months after receiving their Email

Comments