Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of a levofloxacin-tetracycline-based quadriple regimen with a clarithromycin-based regimen to eradicate Helicobacter pylori infection

Protocol summary

Study aim

Comparison of the efficacy of levofloxacin-tetracycline-based four-agents regimen with clarithromycin-based diet in eradicating Helicobacter pylori infection

Design

After selecting the patients, a written consent form is given to the patients and while explaining about the side effects and results of taking the drugs, the patient enters the study. The patient can be excluded from the study at any time, depending on his choice. The duration of these treatment regimens is two weeks, and after the end of antibiotic treatment, treatment with pantoprazole 40 mg bid for four weeks is continued for both groups, and then at the end of the second week after the end of treatment with fecal antigen test will prove .

Settings and conduct

The study site is the gastrointestinal clinic of Imam Khomeini Hospital in Ahvaz

Participants/Inclusion and exclusion criteria

Patients are selected based on clinical complaint and endoscopy, positive RUT test, no previous treatment for H. pylori infection, and no quinolone and macrolide antibiotics during the last two months. Inclusion criteria include all patients with PUD, non-ulcer dyspepsia, and intestinal metaplasia (based on pathology) who are H pylori positive and over 18 years of age. Exclusion criteria are also discontinuation of drugs due to drug side effects or for any reason before one week from the start of the drug.

Intervention groups

These people are divided into two groups based on simple randomization method and will receive two different diets to eradicate their H pylori infection: a group of four-agents-based on levofloxacin-tetracycline-group A ,the other group will be given a clarithromycin-based-group B, quadruple -agents.

Main outcome variables

Eradication drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048038N1**
Registration date: **2020-11-24, 1399/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-24, 1399/09/04**
Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Tahmineh Farbod Ara

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3222 8415

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of a levofloxacin-tetracycline-based quadriple regimen with a clarithromycin-based regimen to eradicate Helicobacter pylori infection

Public title
Comparison of the efficacy of a levofloxacin-tetracycline-based quadriple regimen with a clarithromycin-based regimen to eradicate Helicobacter pylori infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
selection of patients based on clinical complaint of non-ulcer dyspepsia and endoscopy (confirmation of peptic ulcer or pathological confirmation of intestinal metaplasia or gastritis in the field of H. pylori) with a positive RUT test no previous treatment for H. pylori infection no use of quinolone and macrolide antibiotics during the last two months. over 18 years of age.
Exclusion criteria:
Severe side effects of the drug that lead to discontinuation of the drug before completing one week of treatment

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Randomized

Randomization description
These people are based on the method of simple randomization of numbers before starting the study with Random allocation software. No concealment is done for the reader and patients will be assigned to group A or B based on random numbers upon entry.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The diagnosis is based on endoscopic biopsy and rapid urease test (RUT) and is performed by the therapist. After selecting the patients, a written consent form is given to the patients and while explaining about the common side effects and results of taking the drugs, the patient enters the study. The patient can be excluded from the study at any time, depending on his choice. The cost of drugs is provided by the researcher, the drugs are from one brand and will be delivered to the patient. Common side effects leading to discontinuation of the patient or dangerous side effects that require medication should not be continued (for example, nausea and gastrointestinal upset with antibiotics are common, and dangerous side effects such as hypersensitivity reactions, tendonitis). Therefore, in case of leaving the study due to drug side effects, it will be mentioned in the study results. At the end of the fourth week after the treatment, the eradication is confirmed by a stool antigen test, and we will prove the effectiveness of the bacterial eradication treatment. Assessing the patient's acceptance in relation to the correct and complete use of drugs by the therapist and by observing the amount of remaining drugs and asking the patient directly every two weeks by phone and asking about the side effects of drugs, continuing treatment and creating the necessary knowledge about the importance of completing treatment will be done. If the patient takes the full course of fourteen days of antibiotic treatment, it will be considered as a complement to the treatment. All data will be completed in a questionnaire by the therapist (attached at the bottom of the questionnaire).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan Educational and Medical Center, Ahvaz
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Khuzestan Province, Ahvaz Golestan - Farvardin St. - Golestan Educational and Medical Center
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Approval date
2020-11-21, 1399/09/01

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1399.102

Health conditions studied

1

Description of health condition studied
H pylori infection

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Percentage of people with non-ulcer dyspepsia
Timepoint
at initiation of study
Method of measurement
performing upper gastrointestinal endoscopy

2

Description
Percentage of people with intestinal metaplasia
Timepoint
at initiation of study
Method of measurement
performing upper gastrointestinal endoscopy

3

Description
Percentage of people with peptic ulcer disease
Timepoint
at initiation of study
Method of measurement
performing upper gastrointestinal endoscopy

Secondary outcomes

1

Description
H-pylori eradication
Timepoint
after completing treatment
Method of measurement
Stool antigen test for H-pylori

2

Description
Drug side effect
Timepoint
every week
Method of measurement
according to patient

Intervention groups

1

Description
Intervention group: four-agents-based on levofloxacin-tetracycline-group A.Tetracycline-levofloxacin group regimen includes: tetracycline 500 mg every 12 hours, levofloxacin 500 mg daily, bismuth subcitrate 240 mg every 12 hours and pentaprazole 40 mg every 12 hours for 14 days and then pentaprazole at a dose of 40 mg every 12 hours It lasts for four weeks.
Category
Treatment - Drugs

2

Description
Control group: clarithromycin-based-group B, quadruple - agents.. Clarithromycin-amoxicillin regimen includes: clarithromycin 500 mg every 12 hours, amoxicillin 1000 mg every 12 hours, bismuth subcitrate 240 mg every 12 hours, and pentaprazole 40 mg every 12 hours for 14 days, followed by pentaprazole at a dose of 40 mg. Mg every twelve hours for four weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Clinic of Imam Khomeini Hospital in Ahvaz
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Tahmineh Farbod Ara
Position
fellowship of Adult specialist in gastroenterology and adult liver
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available

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

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data is entered in an Excel file and is with the reader, and if other researchers wish, it can be accessed by email after submitting the final article.

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For meta-analysis studies only, citing the source

From where data/document is obtainable

Contact the researcher email pezhmanalavinejad@gmail.com

What processes are involved for a request to access data/document

Contact the researcher email pezhmanalavinejad@gmail.com

Comments