Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The comparison of quinolone-based regimen and conventional quadruple therapy in patients with H.pylori infection

Protocol summary

Summary

H. pylori infection can result to diseases such as peptic ulcer, gastritis, gastric cancer and mucosa-associated lymphoid tissue lymphoma of the stomach. Therefore, its eradication is essential to control these clinical conditions. However, resistance to antibiotics can reduce the eradication success up to 70%.When several attempts to eradicate H.pylori fails, a quinolone such as levofloxacin can be used. Gemifloxacin is a new quinolone that has a much lower MIC than other drugs in this category. So, we conducted a randomized , non-placebo-controlled, multicenter, phase III trial to compare the eradication rate of H.pylori between regular regimen and Gemifloxacin -containing regimen. In this study 140 patients with gastrointestinal discomfort will be evaluated for H. pylori infection, and patients that use antibiotics, bismuth salts or non-steroidal anti-inflammatory drugs during the previous 4 weeks, or had previous gastric surgery, severe systemic diseases, pregnancy and breastfeeding will be excluded. The intervention will take place over a 2-week regimen. Then eradication rate will be compared between groups based on their UBT results.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101311101N1**
Registration date: **2012-11-30, 1391/09/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

Name

Mehrdad Sedigh Ardekani

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Pharmaceutical Sciences Research Center, Faculty of Pharmacy, Shiraz University of Medical Sciences, Professor Alborzi Research Center Shiraz University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of quinolone-based regimen and conventional quadruple therapy in patients with H.pylori infection

Public title

The effect of quinolone-containing regimens for the treatment of Helicobacter pylori infection.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All adult patients with gastrointestinal

discomfort who refer to Namazi Hospital, Shiraz University of Medical Sciences. Exclusion criteria: Previous history of Helicobacter pylori eradication therapy; Consumption of antibiotics, bismuth salts or non-steroidal anti-inflammatory drugs during the past four weeks; previous gastric surgery; severe systemic diseases (such as liver cirrhosis or renal failure); sensitivity to each the antibiotics used in classical therapy; pregnancy and breastfeeding.

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: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Shiraz University of Medical Sciences

Street address
Shiiraz University of Medical Sciences central building, Zand avenue

City
Shiraz

Postal code

Approval date
2012-08-30, 1391/06/09

Ethics committee reference number
CT-91-4703

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
cure rate

Timepoint
1 month after completion of drug therapy

Method of measurement
Urea Breath Test

Secondary outcomes

1

Description
adverse drug reactions

Timepoint
after 2 weeks drug therapy

Method of measurement
patient evaluation

Intervention groups

1

Description
Gemifloxacin,Oral tablet 320 mg, once daily, for 2 weeks

Category
Treatment - Drugs

2

Description
Metronidazol,250 mg, two tablets every 12 hours, for 2 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person

Street address
Namazi Hospital, Namazi Square

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Poostforoosh
Street address
Shiraz University of Medical Sciences central building, Zand Avenue
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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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