

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1235 3733

##### Email address

sharif@sums.ac.ir

##### 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

Shiraz 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****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Laleh Mahmoudi

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Assistant professor of Clinical Pharmacy

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student

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**Fax****Email****Web page address****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*