

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluation of the effect of full mouth disinfection therapy on the recurrence of Helicobacter pylori infection in patients referred to Sayad shirazi hospital in Gorgan

#### Protocol summary

##### Summary

Objectives: To investigate the effect of full mouth disinfection therapy on eradication of Helicobacter pylori from the stomach of the people with gastric ulcer.  
Design: 40 patients with gastric ulcer caused by Helicobacter pylori are selected and divided into two intervention and control groups. Participants including major eligibility criteria: People older than 18 years; at least 10 teeth with the exception of remaining roots and wisdom teeth; gingival index less than 3mm; pocket depth less than or equal to 4 mm; attachment loss less than 5 mm. Intervention: For both treatment groups, routine helicobacter pylori eradication drugs are prescribed. In the intervention group, full mouth oral disinfection is also done . Main outcome measures: Eradication of Helicobacter pylori infection of the stomach of both groups are assessed 4 months after.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080530744N2**  
Registration date: **2017-10-24, 1396/08/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-24, 1396/08/02

##### Registrant information

##### Name

Elham Fakhari

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3227 2253

##### Email address

dr.fakhari@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Golestan University of Medical sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of full mouth disinfection therapy on the recurrence of Helicobacter pylori infection in patients referred to Sayad shirazi hospital in Gorgan

##### Public title

Evaluation of the effect of full mouth disinfection therapy on the recurrence of Helicobacter pylori infection

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Major entry requirements: People older than 18 years; at least 10 teeth with the exception of remaining roots and wisdom teeth; gingival index less than 3 mm; pocket depth less than or equal to 4 mm; attachment loss less than 5 mm. Patient withdrawal conditions from the study : Consumption of antibiotic or proton pump inhibitor in

the past month; Radiation therapy patients; Patients with a history of sensitivity to amoxicillin, clarithromycin, bismuth, omeprazole and chlorhexidine; Patients who once received systemic Helicobacter pylori infection therapy ; Patients with systemic diseases; Pregnant and nursing mothers; smoking

#### Age

From **99 years** old to **57 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

-

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of Golestan University of Medical Sciences

##### Street address

Across Minagol, Valieasr Streets

##### City

Gorgan

##### Postal code

-49169-53363

#### Approval date

2017-08-16, 1396/05/25

#### Ethics committee reference number

IR.goums.REC.1396.131

## Health conditions studied

### 1

#### Description of health condition studied

Stomach ulcer caused by Helicobacter pylori

#### ICD-10 code

-k25

#### ICD-10 code description

-disease of stomach

## Primary outcomes

### 1

#### Description

helicobacter pylori induced gastritis

#### Timepoint

at baseline

#### Method of measurement

Urease test and expert opinion

## Secondary outcomes

### 1

#### Description

-recurrence of helicobacter induced gastritis

#### Timepoint

-4 months after treatment

#### Method of measurement

-respiratory urease test

## Intervention groups

### 1

#### Description

Intervention group: Routine treatment of Helicobacter pylori including bismuth tablet 525 mg (hepatica-Iran) 4 times a day for 2 weeks, Clarithromycin 500 mg tablet (Tehran Chem-Iran) twice a day for 2 Weeks, 20 mg omeprazole capsule (Dr. Obiidi-Iran) 2 times a day for 2 weeks, Amoxicillin 500 mg capsule (Tehran Chem. Iran) 4 times a day for 2 weeks, full mouth oral disinfection therapy including 1- Scaling and root planning in 24-hour intervals with ultrasonic and hand instruments 2- Periodontal pockets irrigation with chlorhexidine (0.12%). 3- Brushing the surface of the tongue with chlorhexidine 0.12% 4- Using chlorhexidine (0.12%) as an oral mouthwash

#### Category

Treatment - Other

### 2

#### Description

Intervention in the control : Routine drug treatment of Helicobacter pylori , including bismuth tablet 525 mg (healing-Iran) 4 times a day For 2 weeks, Clarithromycin Tablet 250 mg (Tehran Chem. Iran) twice a day for 2

weeks, omeprazol capsule 20 mg (Obeidi-Iran) twice a day for 2 weeks, amoxicillin capsule 500 mg(Tehran Chem-Iran) 4 times a day for 2 weeks

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Gastroenterology Sayyad Shirazi Hospital

##### Full name of responsible person

Dr Taghi Amiriani

##### Street address

Sayyad Shirazi Street

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice Chancellor for research, Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Ramzani

##### Street address

Faculty of Dentistry, across Minagol, Valieasr Street

##### City

Gorgan

##### 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, Golestan 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

Faculty of dentistry, Golestan University of Medical

Sciences

##### Full name of responsible person

Dr. Elham Fakhari

##### Position

Assistant Professor of Periodontology, Faculty of Dentistry

##### Other areas of specialty/work

##### Street address

Faculty of Dentistry, across Minagol, Valieasr Street

##### City

Gorgan

##### Postal code

##### Phone

+98 17 3255 5700

##### Fax

##### Email

dr.fakhari@goums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Golestan University of Medical Sciences, Faculty of Dentistry

##### Full name of responsible person

Dr.Elham Fakhari

##### Position

Assistant Professor of Periodontology, Faculty of Dentistry

##### Other areas of specialty/work

##### Street address

Faculty of Dentistry, across Minagol, Valieasr Street

##### City

Gorgan

##### Postal code

##### Phone

+98 17 3255 5700

##### Fax

##### Email

dr.fakhari@goums.ac.irfakhari\_85@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Dr Elham Fakhari

##### Position

Assistant professor

##### Other areas of specialty/work

##### Street address

Faculty of Dentistry, across Minagol, Valieasr Street

##### City

Gorgan

##### Postal code

##### Phone

+98 17 3255 0700

##### Fax

**Email**

Dr.fakhari@goums.ac.irFakhari\_85@yahoo.com

**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*