# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of helicobacter pylori eradication on regression of gastric precancerous lesion in 1st degree relatives of patients with gastric cancer

## Protocol summary

**Summary**

We studied the first degree relatives of gastric cancer patients , aged 40_65 years old, who had gastritis but no peptic ulcer in endoscopy. Their gastritis didn't limit to antrum. Six locations in stomach (lesser curvature_ mid antrum, lesser curvature_ angulus, lesser curvature_ mid body, grater curvature_mid antrum, grater curvature_ angulus, grater curvature _mid body) were biopsied. Patients with precancerous lesions and helicobacter pylori infection were entered into study. from 1020 patients, 480 patients who were entered, were divided into two groups randomaly. 240 patients as case group treated with 500mg Amoxicillin, 20mg Omeprazol, 240 mg Bismute and 500 mg Metronidazol, twice a day, for 2 weeks. 240 patients as control group treated with placebo. Patients were observed with UBT for helicobacter pylori eradication 6_8 weeks later and endoscopy were done for them after one year. Two groups (case_ control) were compared for cancerous lesions after a year.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138706131155N2**
Registration date: **2009-01-30, 1387/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2009-01-30, 1387/11/11

**Registrant information**

**Name**

Farahnaz Joukar

**Name of organization / entity**

Guilan University of Medical Sciences, Gastrointestinal and liver disease Research Center

**Country**

Iran (Islamic Republic of)

**Phone**

+98 13 1553 5116

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**Recruitment status**

**Recruitment complete**

**Funding source**

Gastrointestinal and Liver Diseases Research Center (GLDRC)

**Expected recruitment start date**

2004-08-05, 1383/05/15

**Expected recruitment end date**

2005-08-05, 1384/05/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of helicobacter pylori eradication on regression of gastric precancerous lesion in 1st degree relatives of patients with gastric cancer

**Public title**

Effect of helicobacter pylori eradication on regression of gastric precancerous lesion in 1st degree relatives of patients with gastric cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1st degree relatives of patients with

gastric cancer (father , mother, sister and brother. son and doughter), aged 40-65 years old, with gastritis, dont limit to antrum, and precancerous lesions with helicobacter pylori infection, giving informed consent. Exclusion criteria: cases of gastric cancer, peptic ulcer with endoscopic evidence, history of gasterctomy, chronic or serious medical diseases (renal failure, CHD, liver disease, etc )

**Age**
From **40 years** old to **65 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **480**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

### 1

**Registry name**

**Secondary trial Id**

**Registration date**
2017-11-21, 1396/08/30

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Gastrointestinal and Liver Diseases Research Center

**Street address**
Gastrointestinal and Liver Diseases Research Center-Razi Hospital - Sardar Jangal Ave-Rasht-Iran

**City**
Rasht

**Postal code**
41448-95655

**Approval date**
2004-02-05, 1382/11/16

**Ethics committee reference number**
114

## Health conditions studied

### 1

**Description of health condition studied**
Gasteric Cancer

**ICD-10 code**
c16

**ICD-10 code description**
Malignant neoplasm of stomach

## Primary outcomes

### 1

**Description**
Eradication of helicobacter pylori

**Timepoint**
6-8 weeks after treatment

**Method of measurement**
UBT

### 2

**Description**
Regression of precancerous lesions

**Timepoint**
one year after onset of treatment

**Method of measurement**
endoscopy and pathology

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group reciverd Omeprazol 20mg, Bismut 240mg, metronidazol 500mg,amoxicillin 1gr twice a day for 2 week

**Category**
*empty*

### 2

**Description**
Control group recived plasebo

**Category**
*empty*

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**
Dr.Fariborz Mansour-Ghanaei

**Street address**
Gastrointestinal and Liver Diseases Research Center-

Razi hospital - Sardar Jangal ave.

**City**

Rasht

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Guilan Govermental Province

**Full name of responsible person**

Farahnaz Joukar

**Street address**

Guilan Govermental Province- Moalem ave.

**City**

Rasht

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Guilan Govermental Province

**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**

Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Farahnaz Joukar

**Position**

Assistant of Gastrointestinal and Liver Diseases Research Center

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Dr.Fariborz Mansour-Ghanei

**Position**

Full Professor of Internal Medicine & gastroenterology

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Dr.Helia Valaee Barhagh

**Position**

Doctor/ Researcher

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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*