

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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)

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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 daughter), 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan Governmental Province

Full name of responsible person

Farahnaz Joukar

Street address

Guilan Governmental 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 Governmental 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
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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Full Professor of Internal Medicine & gastroenterology

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

Dr.Helia Valaee Barhagh

Position

Doctor/ Researcher

Other areas of specialty/work

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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