Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of effectiveness of H.pylori eradication on regression of gastric precancerous lesions in the first degree relatives of patients with gastric cancer. A long term double blind randomized controlled clinical trial

Protocol summary

Summary

Aim: The aim of this study is the elucidate the regression of precancerous lesions (atrophy of gastric mucosa or intestinal metaplasia) in stomach by eradication of H. pylori in comparison to Placebo in a double blind randomized clinical trial in subjects having the risk for gastric cancer. Inclusion criteria: all first degree relatives of gastric cancer patients with an age between 40 and 65 years were invited to undergo upper GI endoscopy. From all subjects, biopsy specimens were taken from 5 areas of stomach (2 from antrum and 3 from corpus) for evaluation of gastritis according to update Sidney classification and one from antrum for rapid urease test. All subjects with H. pylori (HP)-positive diffuse gastritis were randomly divided into two groups; one was treated with Placebo and the other received an eradication regimen for 2 weeks (Bismuth Subcitrate, Furazolidone, Metronidazole and Omeprazole). Sample size: By a change of 15% (20% progression under placebo and 10% regression of precancerous lesions after eradication) and by 90% power 315 subjects were needed for each group. Exclusion criteria: all with significant lesions by endoscopy (ulcer, diffuse gastric erosions or erosive duodenits, gastric neoplasia or severe dysplasia verified by histology) or negative HP (Negative urease test and no HP in all specimens) were excluded. Follow Up and outcome: All subjects were followed for endoscopy and biopsy taking as before after 2 and 4 years.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802071852N1**
Registration date: **2009-08-11, 1388/05/20**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2009-08-11, 1388/05/20

Registrant information

Name

Sadegh Massarrat

Name of organization / entity

Digestive Disease Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Shariati Hospital, Digestive Disease Research Center

Expected recruitment start date

2001-05-22, 1380/03/01

Expected recruitment end date

2006-05-22, 1385/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of H.pylori eradication on regression of gastric precancerous lesions in the first degree relatives of patients with gastric cancer. A long

term double blind randomized controlled clinical trial

Public title
Evaluation of effectiveness of H.pylori eradication on regression of gastric precancerous lesions in the first degree relatives of patients with gastric cancer. A long term double blind randomized controlled clinical trial

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: First degree relatives of gastric cancer patients, age between 40 and 65 years, presence of diffuse gastritis, positive urease test Exclusion criteria: significant lesions in stomach (ulcer, diffuse gastric erosions or erosive duodenits, gastric neoplasia or severe dysplasia verified by histology), negative Helicobacter Pylori (Negative urease test and no H. Pylori in all specimens by histology)

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **600**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Interruption of study was planned, when the aim (progression of atrophy or intestinal metaplasia under placebo and regression under eradication by 15%) was achieved at 2 years. No continuation of study will be performed up to 4 years.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee: Digestive Disease Research Center

Street address
Shariati Hospital

City
Tehran

Postal code
14117-13135

Approval date
2000-02-20, 1378/12/01

Ethics committee reference number
3th session of Ethics committee

Health conditions studied

1

Description of health condition studied
Gastric precancerous lesions

ICD-10 code
K31.9

ICD-10 code description
Disease of stomach and duodenum, unspecified

Primary outcomes

1

Description
Course of progression or regression of gastric atrophy and intestinal metaplasia under eradication or placebo treatment

Timepoint
Blood taking, 6 months and 2 and 4 years after first endoscopy and control endoscopy 2 and 4 years after start of trial

Method of measurement
Upper GI endoscopy and taking biopsies from different gastric areas 2 and 4 years after start of study and blood taking before first endoscopy, 6 months and 2 and 4 years after eradication or placebo treatment for determination of H.Pylori antibody and other biomarkers.

Secondary outcomes

1

Description
H.pylori eradication and regression of precancerous lesions (atrophy and intestinal metaplasia) under treatment and progression of precancerous lesions in placebo group

Timepoint
2 and 4 years

Method of measurement
Endoscopy and evaluation of histology according to Sidney classification after 2 and 4 years after begin of study

Intervention groups

1

Description
Omeprazole (2×20 mg, daily in 2 doses), Bismuth subcitrate (4×120 mg, daily in 2 doses), Furazolidone (4×100 mg, daily in 2 doses), Metronidazole (4×250 mg, daily in 2 doses).

Category

Treatment - Drugs

2

Description
Placebo tablets for colloidal Bismuth subcitrate, QID for 2 weeks, Placebo tablet for Furazolidone, QID 1 week, Placebo tablet for Metronidazole, QID for 2 weeks, Placebo caps for Omeprazole, BID for 2 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Digestive Disease Research Center, Tehran University of Medical Sciences
Full name of responsible person
Prof. Sadegh Massarrat
Street address
North Kargar Ave., Shariati Hospital,
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Digestive Disease Research Center, Tehran 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
Digestive Disease Research Center, TUMS
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Person responsible for updating data

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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