

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Histologic evaluation of patients with dysplasia after treatment of Helicobacter pylori result of screening program

Protocol summary

Summary

Histologic evaluation of patients with dysplasia after treatment of helicobacter pylori result of screening program, the study population is all patients over 50 years. Inclusion criteria: all patients over 50 years in the endoscopic evaluation of gastric precancerous lesions in Lashtenesha research project; patients with dysplasia in pathology. Exclusion criteria: Consent to participate in the research. After determining of pathology results, we call to patients with dysplasia then they refer to Gastrointestinal and Liver Diseases Research Center and get treated four drug therapy against helicobacter pylori included: tab clarithromycin 500 miligram one number every 12 hours, cap amoxiciline 500 miligram two numbers every 12 hours, tab bismuth sub citrate 120 miligram two numbers every 12 hours, tab pantoprazol 40 miligram one number daily during two weeks. Patients undergo endoscopy three months after completion of treatment. Two years later, the patient are again done endoscopy and biopsy by specialty gastroenterologist. During endoscopy, five samples are taken from body, angularis, antrum and fundus of stomach and one sample for Rapid Urease Test for helicobacter pylori and evaluation of dysplastic lesions

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406191155N20**
Registration date: **2014-07-25, 1393/05/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-25, 1393/05/03

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

Email address

info@gldrc.org

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2014-03-26, 1393/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histologic evaluation of patients with dysplasia after treatment of Helicobacter pylori result of screening program

Public title

Histologic evaluation of patients with dysplasia after treatment of helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients over 50 years in the endoscopic evaluation of gastric precancerous lesions in

Lashtenesha research project; patients with dysplasia in pathology. Exclusion criteria: No consent to participate in the research.

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Sciences. Ethics Committee Gastrointestinal and Liver Diseases Research

Street address

Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardar Jangal Ave, Rasht, Guilan °

City

Rasht

Postal code

955655-41488

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

ش-175

Health conditions studied**1****Description of health condition studied**

Dysplasia

ICD-10 code

D00.2

ICD-10 code description

Carcinoma in situ of stomach

Primary outcomes**1****Description**

Treatment of helicobacter pylori

Timepoint

Two weeks

Method of measurement

Rapid urease test

Secondary outcomes**1****Description**

Evaluation of dysplasia

Timepoint

Three months after helicobacter treatment

Method of measurement

Endoscopy

Intervention groups**1****Description**

Intervention group take tab clarithromycin 500 miligram one number every 12 hours ,cap amoxiciline 500 miligram two numbers every 12 hours , tab bismuth sub citrate 120 miligram two numbers every 12 hours , tab pantoprazol 40 miligram one number daily

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gastrointestinal clinic of Razi hospital

Full name of responsible person

Farahnaz Joukar

Street address

Gastrointestinal and Liver Diseases Research Center, Razi Hospita, Sardare Jangal Avenue

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vince chancellor for reaserch Guilan University of Medical Sciences

Full name of responsible person

Dr Rasool Tabari KHomeirani

Street address

Sadati st, Namjoo st, Rasht,Guilan

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vince chancellor for reaserch Guilan 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

Gastrointestinal and Liver Disease Research Center(GLDRC)

Full name of responsible person

Farahnaz Joukar

Position

assistant of gastrointestinal and liver disease research center (GLDRC)

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

gastrointestinal and liver disease research center (GLDRC)

Full name of responsible person

Dr.Fariboraz Mansou-Ghanaei

Position

Full Professor of Internal Medicine & Gastroenterology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Gastrointestinal and liver disease research center

Full name of responsible person

Dr. Maryam Bakhshandeh

Position

General Physician

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