

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of clidinium c with triple therapy in comparison with standard triple therapy for helicobacter pylori eradication in peptic ulcer patients

Protocol summary

Summary

Goal: The effect of Clidinium-Chlordiazepoxide (Clidinium- C) on helicobacter pylori (HP) eradication in patients with peptic ulcer. A randomized, not blinded, no placebo controlled, single center, trial phase 2 study. Inclusion criteria: Patients with peptic ulcer in endoscopy and positive rapid urease test for HP infection are enrolled. Exclusion criteria: Patients that are taking non steroid anti-inflammatory drugs (NSAIDs), proton pump inhibitors (PPIs), bismuth preparations or antibiotics during the last four weeks and with prior HP eradication, glaucoma, prostatic hypertrophy, pregnancy , lactation and intolerable side effects of clidinium-c are excluded. Target sample size is 66 patients. HP positive patients receive standard triple therapy of omeprazol 40 milligram (mg), clarithromycin 1 gram (gr) and amoxicillin 2 gr for 2 weeks. Clidinium-c is added for intervention group one tablet before each meal. 6 weeks after therapy ends urease breath test (UBT) is done. Intervention time is spring and summer 1392. In this study the effect of clidinium-c on HP eradication is studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041112977N1**

Registration date: **2013-07-29, 1392/05/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-29, 1392/05/07

Registrant information

Name

Saba Homapour

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 17 1442 1653

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grcgh@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of clidinium c with triple therapy in comparison with standard triple therapy for helicobacter pylori eradication in peptic ulcer patients

Public title

The effect of Clidinium c on peptic ulcer treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with peptic ulcer in endoscopy and positive rapid urease test for helicobacter pylori (HP) infection are enrolled. Exclusion criteria: Patients that are taking non steroid anti-inflammatory drugs (NSAIDs), proton pump inhibitors (PPIs), bismuth preparations or

antibiotics during the last four weeks and with prior HP eradication, glaucoma, prostatic hypertrophy, pregnancy , lactation and intolerable side effects of clidinium-c are excluded.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study randomization is done with table of random numbers.

Secondary Ids

empty

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

Ethics committee of Golestan University of Medical Sciences

Street address

Gorgan, High education department of Falsafi, The Shast kola road, Sari to Gorgan road 5 Kilometer

City

Gorgan

Postal code

4934174515

Approval date

2013-03-17, 1391/12/27

Ethics committee reference number

356191122713

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

peptic ulcer

ICD-10 code

K27

ICD-10 code description

gastroduodenal ulcer NOS peptic ulcer NOS

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

Helicobacter pylori eradication

Timepoint

Before and 8 weeks after intervention

Method of measurement

Before intervention in antrum sample with rapid urease test and 8 weeks after intervention with urease breathe test

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

Age

Timepoint

Before intervention

Method of measurement

Year-Birth certificate

2**Description**

Sex

Timepoint

Before intervention

Method of measurement

Female/male-Observation

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

Intervention 1 : Capsule Omeprazol 40 miligram(mg) (Osveh Pharmaceutical Company) , Tablet (tab)clarithromycine 1 gram(gr) (Chemidarou Pharmaceutical Company) and capsule amoxicilline 2 gr (Kosar Pharmaceutical Company) all daily plus tab clidinium c (Clidinium Bromide 2.5 mg + Chlorodiazepoxide HCL 5 mg)(Sobhan Pharmaceutical Company) one tablet before each meal all of them for 2 weeks.

Category

Treatment - Drugs

2**Description**

Intervention 2 : Capsule Omeprazol 40 miligram(mg) (Osveh Pharmaceutical Company) , Tablet (tab)clarithromycine 1 gram(gr) (Chemidarou Pharmaceutical Company) and capsule amoxicilline 2 gr (Kosar Pharmaceutical Company) all daily for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan 5 Azar Hospital

Full name of responsible person

Mohammad Reza Seyyed Majidi Gastroenterologist/
assistant professor

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Gorgan, 5Azar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of
Medical Sciences

Full name of responsible person

Kamran Haidari , Research Assistant

Street address

Gorgan, High education department of Falsafi, The
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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

Golestan University of Medical Sciences

Full name of responsible person

Saba Homapour

Position

Intern

Other areas of specialty/work**Street address**

Gorgan, High education department of Falsafi, The

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Mohammad Reza Seyyed Majidi

Position

Gastroenterologist/Assistant professor

Other areas of specialty/work**Street address**

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Other areas of specialty/work**Street address**

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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