

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Effects of probiotic and prebiotic composition on standard regimens for H. pylori eradication

Protocol summary

ashosaini@muk.ac.ir

Summary

The aim of the present study is to determine the efficacy of 4 drug regimen with and without Prebiotic and probiotic for H Pylori eradication in patient with peptic ulcer. 4 drug regimens are including: Metronidazole, amoxicillin, omeprazole, Bismuth. Sample size is 60 patients including 30 case and 30 control. Patients has been selected with endoscopically diagnosed duodenal ulcers associated with Helicobacter pylori infection and Rapid Urease test. Cases will take 4 drug regimens as well as Prebiotic and probiotic component in capsules with name of Protexin Protect twice daily for one month. Study is done by Double blind randomized. H Pylori eradication will be done by Urease breath test.

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711231680N1**

Registration date: **2010-02-06, 1388/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-06, 1388/11/17

Registrant information

Name

Ashraf Hosseini

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1613 1362

Email address

Scientific title

Effects of probiotic and prebiotic composition on standard regimens for H. pylori eradication

Public title

Study on H. pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Satisfaction to accompany, Confirmed duodenal ulcers by endoscopy, Positive RUT Exclusion criteria included previous H. pylori eradication therapy or gastric surgery, allergy to drugs, pregnancy, anti fungal treatment and incomplete drug application

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Science,
Sanandaj.Kurdistan, Iran

City

Sanandaj

Postal code

13446- 66177

Approval date

2008-12-23, 1387/10/03

Ethics committee reference number

9045

Health conditions studied

1

Description of health condition studied

H pylori eradication in Duodenal ulcer

ICD-10 code

K26

ICD-10 code description

Duodenal ulcer

Primary outcomes

1

Description

Reducing signs

Timepoint

15 Days

Method of measurement

Medical examination

2

Description

Helicobacter eradication

Timepoint

1 month

Method of measurement

urea breath test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4 drug standard regimens for Iran including: amoxicillin 1 gr twice daily, metronidazole 500 mg twice daily, Omeprazole 20 mg twice daily and bismuth citrate 400mg QID as well as probiotic and prebiotic component (Protexin Protect)

Category

Treatment - Drugs

2

Description

Control group: 4 drug standard regimens and placebo

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kurdistan Digestive Research Center

Full name of responsible person

Dr Ashraf Hosseini

Street address

Tohid hospital

City

Sanandaj

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research Management, Kurdistan University of
Medical Sciences

Full name of responsible person

Dr Haidari

Street address

Research Management, Kurdistan University of
Medical Science, Pasdaran Ave

City

Sanandaj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Management, Kurdistan 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

Kurdestan University of Medical Sciences

Full name of responsible person

Dr Ashraf Hosseini

Position

PhD

Other areas of specialty/work

Street address

Kurdestan University of Medical Sciences

City

Sanandaj

Postal code

66177-13446

Phone

+98 87 1613 1362

Fax

+98 87 1666 4674

Email

ashosaini@muk.ac.ir & ashosaini@yahoo.co.in

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdestan digestive Research Center, Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ashraf Hosseini

Position

PhD, Researcher

Other areas of specialty/work

Street address

Kurdestan University of Medical Sciences

City

Sanandaj

Postal code

66177-13446

Phone

+98 87 1613 1362

Fax

+98 87 1666 4674

Email

ashosaini@muk.ac.ir & ashosaini@yahoo.co.in

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr Ashraf Hosseini

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

Web page address

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