Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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.

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
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Iran (Islamic Republic of)
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+98 87 1613 1362
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ashosaini@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciencs

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

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
Kurdestan University of Medical Sciences

Street address
Kurdestan University of Medical Science, Sanandaj.Kurdestan, 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
Kurdestan 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

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Other areas of specialty/work

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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