

# 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

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##### 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**

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Dr Ashraf Hosseini

**Position**

**Other areas of specialty/work**

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**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*