

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The study on synergism effect of *Cuminum cyminum* L boiled extract with quadruple and triple therapy for eradicated helicobacter pillory in peptic ulcer patients

Protocol summary

Summary

This study is aimed to evaluate synergism effect of *Cuminum cyminum* L boiled extract with quadruple and triple therapy for eradication of helicobacter pillory in peptic ulcer patients. A hundred *Helicobacter pylori* positive peptic ulcer Patients are randomly allocated into five groups. Exclusion criteria in this study are pregnancy, upper gastrointestinal bleeding and any known history of allergic reaction to the drugs. The subjected groups included: 1- *Cuminum* (3g/100cc water) bid and omeprazole 20 mg bid; 2- *Cuminum* (3g/100cc water) b.i.d, omeprazole 20 mg bid, clarithromycin 500mg bid, amoxicillin 500mg qid; 3- *Cuminum* (3g/100cc water) bid and omeprazole 20 mg bid, bismuth subcitrate 120 mg qid, amoxicillin 500mg qid, metronidazole 500 mg bid; 4- omeprazole 20 mg bid, clarithromycin 500mg bid, amoxicillin 500mg qid; 5- omeprazole 20 mg bid, bismuth subcitrate 120 mg qid, amoxicillin 500mg qid, metronidazole 500 mg bid. The treatment period is two weeks. *Helicobacter pylori* eradication is confirmed by 13C-urea breath test 4 weeks after the end of therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071510291N1**
Registration date: **2012-09-09, 1391/06/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-09-09, 1391/06/19

Registrant information

Name

Mohammad Bagher Majnooni

Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study on synergism effect of *Cuminum cyminum* L boiled extract with quadruple and triple therapy for eradicated helicobacter pillory in peptic ulcer patients

Public title

The study on synergism effect of *Cuminum cyminum* L boiled extract with quadruple and triple therapy for eradicated helicobacter pillory

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Urease test was positive; The patient's willingness to cooperate Exclusion criteria: Patients were excluded if they were pregnant; glucose-6 phosphate dehydrogenase (G6PD)-deficient; if they had a history of chronic kidney, liver or lung failure, previous gastrointestinal (GI) surgery, recent upper gastrointestinal bleeding; if they had used non-steroidal anti-inflammatory drug (NSAID) or antibiotic in the past four weeks; if they had any known allergic reaction to drugs used in the treatment regimens; if they were currently breast-feeding.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

the ethics committee of Kermanshah University of Medical Sciences,

Street address

Kermanshah

City

Kermanshah

Postal code

Approval date

2012-06-26, 1391/04/06

Ethics committee reference number

4148/420/7/پ

Health conditions studied

1

Description of health condition studied

peptic ulcer disease induced with H.pylori

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified

Primary outcomes

1

Description

Helicobacter pylori eridication

Timepoint

1 month after treatment

Method of measurement

urea breath test

Secondary outcomes

1

Description

Synergism effect

Timepoint

1 month after treatment

Method of measurement

compare the results of urea breath test

Intervention groups

1

Description

5- omeprazole 20 mg bid, bismuth subcitrate 120 mg qid, amoxicillin 500mg qid, metronidazole 500 mg bid for 14 days.

Category

Treatment - Drugs

2

Description

2 - Cuminum (3g/100cc water) b.i.d, omeprazole 20 mg bid, clarithromycin 500mg bid, amoxicillin 500mg qid, for 14 days.

Category

Treatment - Drugs

3

Description

4- omeprazole 20 mg bid, clarithromycin 500mg bid, amoxicillin 500mg qid for 14 days

Category

Treatment - Drugs

4

Description

3- Cuminum (3g/100cc water) bid and omeprazole 20 mg bid, bismuth subcitrate 120 mg qid, amoxicillin 500mg qid, metronidazole 500 mg bid, for 14 days.

Category

Treatment - Drugs

5**Description**

1- Cuminum (3g/100cc water) bid and omeprazole 20 mg bid for 14 days

Category

Treatment - Drugs

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

Emam Khomeini hospital

Full name of responsible person

Mohammad Bagher Majnooni

Street address

Emam Khomeini hospital, Naghlie, Kermanshah

City

Kermanshah

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

Kermanshah University of Medical Sciences,

Full name of responsible person

Mohammad Bagher Majnooni

Street addressUniversity of Medical Sciences,
Sorkhelige, Kermanshah**City**

Kermanshah

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

Yes

Title of funding source

Kermanshah 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**

Medical Biology Research Center, Kermanshah

University of Medical Sciences, Kermanshah

Full name of responsible person

Dr. Mohammad Bagher Majnooni

Position

Pharm.D/ Researcher

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Person responsible for updating data**Contact****Name of organization / entity**

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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