Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Medical Biology Research Center, Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6473

Email address

mnikbakht@kums.ac.ir

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 Khomini hospital
Full name of responsible person
Mohammad Bagher Majnooni
Street address
Emam Khomini 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 address
University 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
Other areas of specialty/work
Street address
Medical Biology Research Center, P.O.Box:1568, Sorkheh Ligeh, Kermanshah
City
Kermanshah
Postal code
Phone
+98 83 1427 6473
Fax
+98 83 1427 6471
Email
mnikbakht@kums.ac.ir-bagher_1985@yahoo.com
Web page address
www.kums.ac.ir

Person responsible for scientific 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
Other areas of specialty/work
Street address
Medical Biology Research Center, P.O.Box:1568, Sorkheh Ligeh,
City
Kermanshah
Postal code
Phone
+98 83 1427 6473
Fax
Email
mnikbakht@kums.ac.ir- bagher_1985@yahoo.com
Web page address
www.kums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences,
Full name of responsible person
Dr. Mohammad Bagher Majnooni
Position
Pharm.D/ Researcher
Other areas of specialty/work
Street address
Medical Biology Research Center, P.O.Box:1568, Sorkheh Ligeh,
City

Kermanshah
Postal code
Phone
+98 83 1427 6473
Fax
Email
mnikbakht@kums.ac.ir-bagher_1985@yahoo.com
Web page address
www.kums.ac.ir

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