Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Thyme combined effect of triple therapy regimen compared with the standard regimen alone in eradication of Helicobacter pylori infection in patients who referred with upper gastrointestinal symptoms.

Protocol summary

Summary

Objectives According to the high incidence of Helicobacter pylori infection in Iran and antimicrobial effects of thyme, we aim to compare the rate of Helicobacter pylori eradication by standard regime and standard therapeutic regime plus thyme. Design This study is a not blinded clinical trial and patients after informed consent enroll in study and divide in two groups for interventions. Setting and conduct All subjects who fulfill our inclusion criteria randomly divide in two groups (30 patients in each group) and therapeutic interventions will perform. Participants including main inclusion criteria Patients with gastrointestinal symptoms who have upper gastrointestinal endoscopy with a positive urea breath test will enroll in study. Intervention Intervention group will receive a regimen including pantoprazole, amoxicillin, clarithromycin and thyme (gastrolite) and the control group will receive pantoprazole, amoxicillin, clarithromycin and placebo (instead of thyme). The dose of the prescribed drugs are as follows: pantoprazole tablets 40 mg two times per day, amoxicillin 1 g capsule two times per day, clarithromycin 500 mg capsules two times per day and thyme as capsule (gastrolite) every 8 hours and in the control group a placebo with similar appearance for 2 weeks. Then the pantoprazole (40 mg daily) continue for another two weeks, then after a two weeks washout period to avoid from false negative response, urea breath test is performed and results will be recorded. Main outcome variables Helicobacter pylori eradication (based on urea breath test)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102024625N1**

Registration date: **2016-02-17, 1394/11/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-17, 1394/11/28

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Semnan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Thyme combined effect of triple therapy regimen compared with the standard regimen alone in eradication of Helicobacter pylori infection in patients who referred

with upper gastrointestinal symptoms.

Public title
Thyme combined effect of triple therapy regimen compared with the standard regimen alone in eradication of Helicobacter pylori infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Positive result for urea breath test
Exclusion criteria: Receiving of Helicobacter pylori eradication therapy during past six months.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethics Committee of Semnan University of Medical Sciences
Street address
Basij Boulvard, In front of governor
City
Semnan
Postal code
3519747167
Approval date
2015-05-19, 1394/02/29
Ethics committee reference number
IR.SEMUMS.REC.1394.8

Health conditions studied

1

Description of health condition studied
Helicobacter pylori eradication
ICD-10 code
B98.0
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Negative urea breath test
Timepoint
Six weeks after initiation of interventions
Method of measurement
Urea breath test

Secondary outcomes

1

Description
Eradication of Helicobacter pylori infection
Timepoint
Six weeks after interventions
Method of measurement
Urea breath test

Intervention groups

1

Description
Control group will receive a regimen including pantoprazole tablets 40 mg two times per day, amoxicillin 1 g capsule two times per day, clarithromycin 500 mg capsules two times per day and a placebo with similar appearance for 2 weeks. Then the pantoprazole (40 mg daily) continue for another two weeks, then after a two weeks washout period to avoid from false negative response, urea breath test is performed and results will be recorded.
Category
Placebo

2

Description
Intervention group will receive a regimen including pantoprazole tablets 40 mg two times per day, amoxicillin 1 g capsule two times per day, clarithromycin 500 mg capsules two times per day and thyme as capsule (gastrolite) every 8 hours. Then the pantoprazole (40 mg daily) continue for another two weeks, then after a two weeks washout period to avoid from false negative response, urea breath test is performed and results will be recorded.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Ramin Seyfollahpoor
Street address
Basidj Boulevard, Amin Avenue
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Sciences
Full name of responsible person
Mohammad Reza Asgari
Street address
Basij Bulvard
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Semnan 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Atosa Najmoddin
Position
Internist/ Assisstant professor
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Kowsar hospital, Amin Avenue, Basidj Boulevard
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Mehrdad Zahmatkesh
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Research expert
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Kowsar Hospital, Amin Avenue, Basidj Boulevard
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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