

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Registration timing: **registered_while_recruiting**

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)

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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102024625N1**

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

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 Boulevard, 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

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Basij Bulvard

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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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Research expert

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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