

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial on the effects of green tea extract plus triple therapy regimen compared with triple therapy regimen on eradication of helicobacter Pylori in in patients diagnosed with helicobacter Pylori infection

Protocol summary

Summary

This study compares the effects of triple therapy plus green tea extract regimen and the triple therapy regimen on eradication of helicobacter Pylori in patients diagnosed with helicobacter Pylori infection. A total of 60 outpatients infected with Helicobacter pylori who referred to the Gestation Clinic of Vali-e Asr Hospital of Birjand in 2016 were selected by convenience sampling method. The major inclusion criteria consisted of positive result of urease breath test (UBT) and rapid urease test for diagnosis of helicobacter pylori and having indications for Helicobacter pylori treatment. The participants were assigned into intervention and control groups (n = 30 per group) via simple allocation method. The intervention group received the routine triple therapy plus green tea extract pills (450 mg twice daily) for two weeks. The control group only received the routine triple therapy regimen for two weeks. Four weeks after completion of intervention, urease breath test was performed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061317756N18**

Registration date: **2017-07-10, 1396/04/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-10, 1396/04/19

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Birjand University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on the effects of green tea extract plus triple therapy regimen compared with triple therapy regimen on eradication of helicobacter Pylori in in patients diagnosed with helicobacter Pylori infection

Public title

Eradication of helicobacter Pylori in triple therapy regimen supplemented by green tea extract compared with routine triple therapy regimen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Positive result of urease breath test (UBT) and/or rapid urease test for diagnosis of helicobacter pylori; having indications for Helicobacter pylori treatment; willingness to cooperate in the study; lack of green tea consumption by the patient prior to the study onset; no history of macrolide. Exclusion criteria: Previous treatment for helicobacter pylori; consumption of proton pump inhibitors from a month before the test, or blockers of H2 receptor 24 hours before the test, or antibiotics and bismuth from two weeks before the test; pregnancy; malignancy; gastrectomy; severe liver disease or any other severe disease within the past two years; any sensitivity to penicillin or other substances used in the medication regimen; incomplete consumption of the drugs for any reason.

Age

No age limit

Gender

Both

Phase

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice-chancellery of Research and Technology, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Postal code

Approval date

2016-03-08, 1394/12/18

Ethics committee reference number

lr.bums.REC.1395.288

Health conditions studied

1

Description of health condition studied

Helicobacter pylori

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

Eradication of helicobacter pylori

Timepoint

Four weeks after intervention was completed

Method of measurement

Urease breath test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The intervention group received the routine triple therapy regimen plus green tea extract pill (450 mg twice daily) for two weeks. Four weeks after completion of intervention, urease breath test was performed.

Category

Treatment - Drugs

2

Description

Control Group: The control group only received the routine triple therapy regimen for two weeks. Four weeks after completion of intervention, urease breath test was performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gestation Clinic of Vali-e Asr Hospital

Full name of responsible person

Street address

Vali-e Asr Hospital, Ghaffari St.,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology at
Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

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Vice-chancellery of Reasearch and Technology,
Birjand University of Medical Sciences, Ghaffari St.,

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Birjand,

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology at Birjand
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**

Birjand University of Medical Sciences

Full name of responsible person

Laila Omidvar

Position

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PhD Candidate in Translation Studies

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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