

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3239 5680

##### Email address

mbroozgar@bums.ac.ir

##### 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

**Street address**

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

**City**

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**

Assistant of Internal Diseases

**Other areas of specialty/work****Street address**

Faculty of Medicine, Birjand University of Medical  
Sciences, Ghaffari St.,

**City**

Birjand,

**Postal code****Phone**

+98 56 3239 5680

**Fax****Email**

Roozgar@bums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Laila Omidvar

**Position**

Assistant of Internal Diseases

**Other areas of specialty/work****Street address**

Faculty of Medicine, Birjand University of Medical  
Sciecnes, Ghaffari St.,

**City**

Birjand,

**Postal code****Phone**

+98 56 3239 5680

**Fax****Email**

roozgar@bums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Roozgar

**Position**

PhD Candidate in Translation Studies

**Other areas of specialty/work****Street address**

Vive-chancellery of Education, Birjand University of  
Medical Sciences, Ghaffari St.,

**City**

Birjand,

**Postal code****Phone**

+98 56 3239 5680

**Fax****Email**

hadirooz@gmail.com

**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*