

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Rosa Damascena Extract in treatment and eradication of asymptomatic Helicobacter pylori infection in children

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of Rosa Damascena Extract in the treatment and eradication of asymptomatic Helicobacter Pylori infection in children 9 to 15 years old of Birjand. The sample of this study is 200 people including 100 cases and 100 control subjects. The main inclusion criteria of this study are age between 9 to 15 years old and being a resident of Birjand. The main exclusion criteria are gastrointestinal symptoms requiring treatment, antibiotic use in the last month, taking antacids, diarrhea, immunodeficiency and food and drug allergy. The study duration is 6 months that during this period the case group will be treated with Rosa Damascena Extract (as the studying intervention) and the control group will receive a mixture of starch and sugar as a placebo. Before and after the intervention stool samples study for the presence of H.pylori antigens on all patients will be carried out in order to monitor the outcome of the study (quantitative amount of Helicobacter pylori antigen in stool).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016052328012N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-23, 1395/10/03

##### Registrant information

###### Name

Hadi Moulaei

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 32433001

###### Email address

moulaei.h@ajums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Birjand University of Medical Sciences

###### Expected recruitment start date

2016-09-10, 1395/06/20

###### Expected recruitment end date

2016-11-20, 1395/08/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of Rosa Damascena Extract in treatment and eradication of asymptomatic Helicobacter pylori infection in children

###### Public title

Effect of Rosa Damascena Extract in treatment and eradication of asymptomatic Helicobacter pylori infection in 9-15 years old children of Birjand

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: age between 9 to 15 years old; Residence of Birjand; Consent to participate in the study  
Exclusion criteria: unwillingness to participate; gastrointestinal signs that require treatment; use of antibiotics in last month; taking antacids drugs (PPI and H2blocker); diarrhea; immunodeficiency; food and drug

allergy.

### Age

From **9 years** old to **15 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **200**

### 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

Birjand University of Medical Sciences

##### Street address

Moalem Blvd

##### City

Birjand

##### Postal code

9717853577

#### Approval date

2016-04-27, 1395/02/08

#### Ethics committee reference number

ir.bums.1395.7

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacter Pylori Infection

#### 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

Quantitative amount of Helicobacter pylori antigen in stool sample

#### Timepoint

before intervention - after intervention

#### Method of measurement

Laboratory result

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Case (intervention) group: after training on drug consumption and emphasis on contact the physician if confronted with drug side effects, they will treated with Rosa Damascena Extract with 20 mg daily per kilogram twice a day for 14 days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group will treated with placebo (a mixture of starch and sugar), for 14 days.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Elementary and High schools of Birjand City

##### Full name of responsible person

Dr. Hadi Moulaei

##### Street address

Moallem Blvd

##### City

Birjand

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for research - Birjand University of Medical Sciences

##### Full name of responsible person

Doctor Zarban

##### Street address

Moallem Blvd

##### City

Birjand

**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 - 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**

Dr. Hadi Moulaei

**Position**

Resident of Pediatrics

**Other areas of specialty/work**

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Associate Professor

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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*