

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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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
Elemetary 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
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Full name of responsible person
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Person responsible for scientific inquiries

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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