

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Role of saccharomyces boulardi in eradication of Helicobacter Pylori infection in 9-12 year old asymptomatic children live in Birjand

Protocol summary

Summary

the goal of this study is to improve treatment results of helicobacter pylori infection in children and to suggest a new treatment method for this infection. every student between 9-12 year have the inclusion criteria and the exclusion criterias are disagreement to be a participant, significant GI sign and symptom, antibiotic usage in the last month, history of antacid usage, diarrhea at the time of sampling, history of immunodeficiency, history of any drug or food allergy, and antibiotic usage during the time of intervention. the study population is asymptomatic students with positive results of stool antigen that has been detected in screening previously. sample size of 20 for each group (intervention and control) considered and sampling will be done randomly from the population. the intervention is treatment with capsules of dried saccharomyces boulardi with Yomogi trade name. both intervention and placebo groups receive medication for 1 month. follow up with telephone contacts will be done. at the end of this time stool analysis for Helicobacter pylori stool antigen will be done once again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052117791N1**

Registration date: **2014-06-23, 1393/04/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-23, 1393/04/02

Registrant information

Name

Fatemeh Basirinejad

Name of organization / entity

Birjand University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 56 1882 5000

Email address

fateme.basiri@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Science

Expected recruitment start date

2014-06-08, 1393/03/18

Expected recruitment end date

2014-06-15, 1393/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of saccharomyces boulardi in eradication of Helicobacter Pylori infection in 9-12 year old asymptomatic children live in Birjand

Public title

Role of probiotics on eradication of helicobacter pylori in children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 9-12 year old children who study in Birjands grade schools exclusion criteria: dissatisfaction in cooperation; significant gastrointestinal sign and symptom; antibiotic usage in previous month; history of antacid usage (PPI or H2 blocker); diarrhea at the time of

sampling;history of any immunodeficiency;any kind of food and drug allergy; use of antibiotics for other diseases in time of intervention in case and control group

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Birjand University of Medical Science

Street address

ghaffari street,birjand,iran

City

Birjand

Postal code

Approval date

2014-05-04, 1393/02/14

Ethics committee reference number

05-02-1393

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

B98.0 Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

H.pylori stool antigen

Timepoint

before and at the end of intervention

Method of measurement

quantitative in microgram/ml

Secondary outcomes

1

Description

incidence of diarrhea due to intervention

Timepoint

at the end of intervention

Method of measurement

questionnaire

2

Description

incidence of improvement in weight gaining due to intervention

Timepoint

at the end of intervention

Method of measurement

questionnaire

3

Description

incidence of improvement in bowel habit due to intervention

Timepoint

at the end of intervention

Method of measurement

questionnaire

4

Description

incidence of vomiting due to intervention

Timepoint

at the end of intervention

Method of measurement

questionnaire

5

Description

incidence of flatulence due to intervention

Timepoint

at the end of intervention

Method of measurement

questionnaire

6

Description

incidence of fever due to intervention

Timepoint

at the end of intervention
Method of measurement
questionnaire

7

Description
incidence of abdominal pain due to intervention
Timepoint
at the end of intervention
Method of measurement
questionnaire

8

Description
incidence of other bad effects due to intervention
Timepoint
at the end of intervention
Method of measurement
questionnaire

9

Description
incidence of improvement in appetite due to intervention
Timepoint
at the end of intervention
Method of measurement
questionnaire

10

Description
incidence of other good effects due to intervention
Timepoint
at the end of intervention
Method of measurement
questionnaire

11

Description
incidence of nausea due to intervention
Timepoint
at the end of intervention
Method of measurement
questionnaire

Intervention groups

1

Description
yomogi,250mg capsules contain dried yeast of
saccharomyces boulardi,once daily,for one month
Category
Treatment - Drugs

2

Description
placebo,250mg capsules contain lactose and starch

powder,once daily,for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
maryam female grade school
Full name of responsible person
Mrs Behdani the school manager
Street address
Adl street,Birjand
City
Birjand

2

Recruitment center
Name of recruitment center
Emam Hosein female grade school
Full name of responsible person
Street address
Moallem street, birjand
City
Birjand

3

Recruitment center
Name of recruitment center
Atefe female grade school
Full name of responsible person
Mrs Kamal the school manager
Street address
Samadi street,Birjand
City
Birjand

4

Recruitment center
Name of recruitment center
Younes Fatemi female grade school
Full name of responsible person
Mrs Namakin the school manager
Street address
14 alley, zafar street,Birjand
City
Birjand

5

Recruitment center
Name of recruitment center
Behesht female grade school
Full name of responsible person
Mrs Eslami health teacher
Street address
Mehr shahr
City

Birjand

6

Recruitment center

Name of recruitment center

Roghaye female grade school

Full name of responsible person

Mrs Ansari fard the school manager

Street address

Shahid beheshti street

City

Birjand

7

Recruitment center

Name of recruitment center

Gol narges female grade school

Full name of responsible person

Mrs tavakkoli the school manager

Street address

8th alley, sadaf street, Birjand

City

Birjand

8

Recruitment center

Name of recruitment center

Shahed female grade school

Full name of responsible person

Street address

City

Birjand

9

Recruitment center

Name of recruitment center

Sama male grade school

Full name of responsible person

Mr ghafari the school manager

Street address

Moallem street

City

Birjand

10

Recruitment center

Name of recruitment center

Hakim Nazari male grade school

Full name of responsible person

Mr Rabi the school manager

Street address

Hakim Nazari street

City

Birjand

11

Recruitment center

Name of recruitment center

Barkat male grade school

Full name of responsible person

Mrs Eslami the health teacher

Street address

Mehr shahr

City

Birjand

12

Recruitment center

Name of recruitment center

Darololum male grade school

Full name of responsible person

Mr Hasani the school manager

Street address

Sadaf street

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Science

Full name of responsible person

Dr Zarban, assistant of deputy of research and technology of Birjand university of medical science

Street address

Ghaffari street, birjand

City

Birjand

Grant name

Grant code / Reference number

718

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand University of Medical Science

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 Science

Full name of responsible person

Fatemeh Basirinejad

Position

pediatric disease assistant

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

number 258,12th alley,seyed razi street,Vakil abad
avenue,Mashhad,IRAN

City

Mashhad

Postal code**Phone**

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Fax**Email**

fateme.basiri@bums.ac.irfatemehbasirinejad@gmail.c
om

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Science

Full name of responsible person

Kokab Namakin

Position

associate professor

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

Valiasr hospital,ghaffari street,Birjand

City

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+98 56 1444 3000

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d_namakin@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Science

Full name of responsible person

Fatemeh Basirinejad

Position

pediatric disease assistant

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

number 258,12th alley,Seyed razi
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City

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fateme.basiri@bums.ac.irfatemehbasirinejad@gmail.c
om

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