Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Role of saccharomycess 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 saccharomycess 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

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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 saccharomycess 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 antiacid 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 vomitting due to intervention

Timepoint
at the end of interventin

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
qustionnaire

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 saccharromyces 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 ghafuri 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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Science
Full name of responsible person
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Position
associate professor
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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fateme.basiri@bums.ac.irfatemehbasirinejad@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