

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of yeast probiotic (*saccharomyces boulardii*) on acute diarrhea in children

Protocol summary

Summary

This study will be conducted to determine the effect of yeast probiotic (*saccharomyces boulardii*) on acute diarrhea in children. Inclusion criteria : existence of acute diarrhea (watery diarrhea 3 times or more/ day that last less than 14 days); mild and moderate dehydration; age between 2-5 years ; Failure to receive antibiotics and probiotic compounds in the past 1 month . Exclusion criteria: chronic diarrhea; malabsorption diseases (such as dairy and gluten intolerance such as bread , barley and oat); dysentery(diarrhea with visible blood); accompanying disease (such as diabetes, malnutrition, celiac, dairy intolerance); severe dehydration (more than 9%); abdominal distention; suspected to intestinal obstruction ; vomiting. In this study, two groups of case and control (each group 30 patients) affected with acute diarrhea will be evaluated. The total of patients that will be evaluated are 60 patients. The case group will receive yeast probiotic *saccharomyces boulardii* (trade name yomog cap) and control group will receive placebo(Chickpea flour powder). Intervention time will be from 22/11/2017 until 21/9/2018. The Primary outcome including frequency of diarrhea will be compared between groups.

General information

Acronym

yeast probiotic (*saccharomyces boulardii*) and acute diarrhea

IRCT registration information

IRCT registration number: **IRCT2017090812897N3**

Registration date: **2017-10-07, 1396/07/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-07, 1396/07/15

Registrant information

Name

Abolfazl Mahyar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28133348089

Email address

amahyar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Department of Qazvin University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of yeast probiotic (*saccharomyces boulardii*) on acute diarrhea in children

Public title

The effect of yeast probiotic (*saccharomyces boulardii*) on acute diarrhea in children

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: existence of acute diarrhea; mild and

moderate dehydration; age between 2-5 years ; Failure to receive antibiotics and probiotic compounds in the past 1 month . Exclusion criteria: chronic diarrhea; malabsorption diseases ;dysentery;accompanying diseasesuch as diabetes; severe dehydration ;abdominal distention; suspected to intestinal obstruction; vomiting)

Age

From **2 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Qazvin University of Medical Sciences

Street address

Bolvar Shahid Bahonar,Qazvin University of medical sciences-Qazvin

City

Qazvin

Postal code

59811-34197

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.QUMS.REC.1396.239

Health conditions studied

1

Description of health condition studied

Acute diarrhea

ICD-10 code

A03

ICD-10 code description

Shigellosis

Primary outcomes

1

Description

frequency of diarrhea

Timepoint

before intervention, afterintervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

duration of diarrhea

Timepoint

before intervention, after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

The case group will be receive cap Yomogi (contains 250 mg dried yeast *Saccharomyces boulardii*) as a single dose per day. Cap Yomogi is produced by ARDEYPHARM GmbH company under the license No. 640920, Herdecke , Germany. For easier eating of probiotics the content of cap yomogi will be dissolved in 10 ml of water.

Category

Treatment - Drugs

2

Description

The control group will receive Chickpea flour powder as a single dose per day. Chickpea flour powder is produced by Tarkhineh Company under the license No. 640920 and Operation license No.81, Tehran, Iran. For easier eating, the Chickpea flour powder will be dissolved in 10 ml of water. The color ,taste and volume of Chickpea flour powder will be similar of cap Yomogi.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Abolfazl Mahyar

Street address

Valiasr square-Qods hospital

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Shamekhi

Street address

Research Department-Medical College-Qazvin
University of Medical Sciences

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences, Qazvin

Full name of responsible person

Abolfazl Mahyar

Position

Pediatrician-professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Abolfazl Mahyar

Position

Pediatrician-professor

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Full name of responsible person

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Position

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Other areas of specialty/work

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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