

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of probiotic effect with placebo in prevention of recurrence of intestinal bacterial overgrowth in the irritable bowel syndrome patients

Protocol summary

Summary

Objective: comparison of probiotics effect with placebo in prevention of recurrence of small intestinal bacterial overgrowth in patients with irritable bowel syndrome. One hundred seventy two patients with irritable bowel syndrome based on ROME III criteria and small intestinal bacterial overgrowth based on positive breath test referred to gastroenterology clinic were assessed. These patients were enrolled in study after exclusion of important gastrointestinal diseases based on history, physical exam and lab tests and they were excluded if they had sensitivity to antibiotics, pregnancy, lactation, previous abdominal surgery, past medical history of hypothyroidism, malignancies, renal and liver insufficiency, diabetes, familial history of colorectal carcinoma, ingestion of immunosuppressives and antibiotics in recent 2 months and ingestion of probiotics for more than 2 weeks in recent 6 months. These patients received a 10 days period of antibiotics initially and then after a negative breath test they were divided into 2 groups (probiotic and placebo) randomly based on random number tables. One group received mutaflor probiotic included of 8/74-68/43 mg EColi nissle 1917 strain made by Ardeypharm GmbH company in Germany, one capsule per day and the other group received placebo made by Ahvaz Jondishapour Pharmacy University similar to probiotic, one capsule per day for 3 months. After 3 months treatment with probiotic or placebo, recurrence of small intestinal bacterial overgrowth was assessed by repetition of hydrogen breath test and was compared between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122815959N1**

Registration date: **2014-01-10, 1392/10/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-10, 1392/10/20

Registrant information

Name

Sam Shahinzadeh

Name of organization / entity

Ahvaz Jondishapour University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 622 1620

Email address

shahinzadeh.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jondishapour University of Medical Science

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2013-07-30, 1392/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of probiotic effect with placebo in prevention of recurrence of intestinal bacterial overgrowth in the irritable bowel syndrome patients

Public title

Effect of probiotic in intestinal bacterial overgrowth in the irritable bowel syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with irritable bowel syndrome based on ROME III criteria and small intestinal bacterial overgrowth based on positive hydrogen breath test.

Exclusion criteria: patients with sensitivity to antibiotics, pregnancy, lactation, previous abdominal surgery, past medical history of hypothyroidism, celiac, malignancy, renal and liver insufficiency, diabetes and inflammatory bowel disease, familial history of colorectal carcinoma, ingestion of immunosuppressives and antibiotics in recent 2 months, ingestion of probiotics for more than 2 weeks in recent 6 months.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **172**

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

Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Golestan boulevard, Jondishapour University Center

City

Ahvaz

Postal code

Approval date

2013-12-04, 1392/09/13

Ethics committee reference number

ajums.REC.1392.181

Health conditions studied

1

Description of health condition studied

Treatment of Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Expiratory hydrogen

Timepoint

After 10 days treatment with antibiotics and after 3 months treatment with probiotic

Method of measurement

Expiratory hydrogen with micro H2 and hydrazine hydrogen breath test after ingestion of 1 gram per kilogram body weight glucose in 150 ml water based on ppm

Secondary outcomes

1

Description

Incidence of adverse effects of probiotic

Timepoint

At the end of third month of treatment

Method of measurement

Asking from patients

Intervention groups

1

Description

Placebo made by Ahvaz Jondishapour Pharmacy University like probiotic capsule, ingestion one capsule per day for 3 months

Category

Treatment - Drugs

2

Description

Mutaflor probiotic include 8/74-68/43 mg Ecoli Nissle 1917 strain made by Ardeypharm GmbH Company in Germany, ingestion of one capsule per day for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic of Ahvaz Imam Khomeini

Hospital
Full name of responsible person
Jadbabaie Maryam
Street address
20 meters Street, Imam Khomeini Hospital
City
Ahvaz

Email
samsorena@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Shahinzadeh Sam
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Ahvaz Jondishapour University of Medical Sciences
Full name of responsible person
Feghi Mostafa
Street address
Golestan Boulevard, University center, Vice chancellor for research
City
Ahvaz
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 of Ahvaz Jondishapour 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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Person responsible for updating data

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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