

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Double Blind Randomized Clinical Trail: Comparing Lactobacillus plantarum 299v with Placebo in treating irritable bowel syndrome patients

Protocol summary

Study aim

The aim of the present study was to assess the efficacy L. Plantarum 299v against in local population suffering from IBS with improved study design and larger sample size.

Design

This was a double blind placebo-controlled study, conducted for six (6) months Randomization was started by lottery method and then patients were alternatively allotted to either of the two groups. All the patients received probiotics (L. Plantarum 299v) or placebo for four (4) weeks and had three follow up visits after the baseline investigation. The baseline and the first follow up after two weeks were carried out.

Settings and conduct

The patients were recruited through the outpatient clinic of Gastroenterology and Hepatology Department of the Lady Reading Hospital, Peshawar

Participants/Inclusion and exclusion criteria

All the adult patients of either gender fulfilling the Rome III criteria for IBS, willing to participate and committed for follow up throughout the study period were enrolled in the study. The patients having history of major abdominal surgery, organic intestinal disease or chronic infectious disease like HIV or tuberculosis were excluded from the study. The pregnant and the female breastfeeding their babies or anyone with current use of antibiotics were also not included in the study population.

Intervention groups

The study drug containing 5x10¹⁰ cfu of L.Plantarum 299v and the placebo containing micro-crystalline cellulose powder, both were packed in the similar packing by the manufacturers (Genetex Pharma PVT Limited). The study drug was labeled A and the placebo as B. Both groups were treated with their respective medicine/placebo. It was disclosed at the end of the

study.

Main outcome variables

This randomized trail failed to show any significant improvement in the IBS symptoms by the use of L. Plantarum as compared to placebo.

General information

Reason for update

Acronym

RCT in IBS

IRCT registration information

IRCT registration number: **IRCT20200504047303N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **prospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Muhammad Kamran Hassan

Name of organization / entity

Lady Reading Hospital Peshawar

Country

Pakistan

Phone

+92 91 9211430

Email address

drkamran177@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2635-10-10, 2014/07/18

Expected recruitment end date

2636-04-07, 2015/01/18

Actual recruitment start date

2635-10-12, 2014/07/20

Actual recruitment end date

2636-04-09, 2015/01/20

Trial completion date

2636-04-09, 2015/01/20

Scientific title

A Double Blind Randomized Clinical Trail: Comparing Lactobacillus plantarum 299v with Placebo in treating irritable bowel syndrome patients

Public title

Comparing Lactobacillus plantarum 299v with Placebo in treating irritable bowel syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Fulfilling the Rome III criteria for IBS Willing to participate Committed for follow up throughout the study period

Exclusion criteria:

History of major abdominal surgery, Organic intestinal disease or chronic infectious disease like HIV or tuberculosis Pregnant and the female breastfeeding their babies Anyone with current use of antibiotics

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **190**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After fulfilling the inclusion criteria for the study and signing the informed consent form the randomization was started by lottery method and then patients were alternatively allotted to either of the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The study drug containing 5x10¹⁰ cfu of L.Plantarum 299v and the placebo containing micro-crystalline cellulose powder, both were packed in the similar packing by the manufacturers (Genetex Pharma PVT Limited). The study drug was labeled A and the placebo as B, it was disclosed at the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

NA

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Research and Ethics Board of Lady Reading Hospital Peshawar

Street address

Lady Reading Hospital Peshawar

City

Peshawar

Postal code

25000

Approval date

2635-10-10, 2014/07/18

Ethics committee reference number

31/IREB/PGMI/LRH

Health conditions studied**1****Description of health condition studied**

irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes**1****Description**

Symptomatic treatment with out Lactobacillus plantarum 299v

Timepoint

conducted for six (6) months

Method of measurement

Daily frequency of abdominal pain was considered as primary end point. The secondary end points were improvement in the severity of abdominal pain, severity of the bloating and feeling of partial rectal emptying. Both the primary and the secondary end points were gauged on the visual analogue scale from zero (0) to ten (10), 0 being normal and 10 being very severe. In each visit the patients were examined thoroughly and all the parameters were noted along with the medication compliance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients enrolled suffering from IBS were divided in two groups Group A received Lactobacillus plantarum 299v.

Category

Treatment - Drugs

2

Description

Control group: Patients enrolled suffering from IBS were divided in two groups Group B received Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Hepatology Department of the Lady Reading Hospital, Peshawar

Full name of responsible person

Dr. Muhammad Kamran Hassan

Street address

Lady Reading Hospital, Peshawar

City

Peshawar

Postal code

25000

Phone

+92 91 9211430

Email

drkamran177@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Genetics Pharma PVT

Full name of responsible person

NA

Street address

39 A, Sunder Industrial Estate, Off Raiwind Road. Sundar Industrial Estate, Lahore, Punjab

City

Peshawar

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54000

Phone

+92 42 35297761

Fax

+92 42 35297761

Email

info@genetics-pharmaceuticals.com

Grant name

Grant code / Reference number

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

No

Title of funding source

NA

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Lady Reading Hospital, Peshawar

Full name of responsible person

Dr Muhammad Kamran Hassan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gastroenterology and hepatology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the form of publish article

When the data will become available and for how long

In the form of publish article as soon as the article publish

To whom data/document is available

To all

Under which criteria data/document could be used

would be freely available for download

From where data/document is obtainable

on request from corresponding author

What processes are involved for a request to access data/document

email to the corresponding author

Comments

This retrospective trial registration