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 therir 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
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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
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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 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