

# Clinical trial of Biotherapi®, a probiotic supplement, as an additional therapy in the treatment of rheumatoid arthritis

<b>Submission date</b> 29/09/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/07/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rheumatoid arthritis (RA) is a long-term condition that causes pain, swelling and stiffness in the joints. The condition usually affects the hands, feet and wrists.

Probiotics are live bacteria and yeasts that are good for you, especially your digestive system. The use of probiotics to prevent or treat arthritis is unexplored but some studies have indicated the potential benefit. Oral treatment with probiotics has been shown to decrease the severity of arthritis symptoms.

### Who can participate?

Adults aged 18 to 75, diagnosed with RA.

### What does the study involve?

Participants will be randomly allocated to receive treatment as usual with or without probiotic supplement (capsules) for rheumatoid arthritis for 90 days.

### What are the possible benefits and risks of participating?

There are no side effects or risk due to participation in this study.

### Where is the study run from?

Yashoda Hospitals, Secunderabad (India)

### When is the study starting and how long is it expected to run for?

August 2017 to July 2019

### Who is funding the study?

Investigator-initiated and funded

### Who is the main contact?

Dr Arindam Nandy Roy, [doctor.arindam@yahoo.com](mailto:doctor.arindam@yahoo.com)

# Contact information

**Type(s)**

Public

**Contact name**

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# Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

# Study information

**Scientific Title**

A prospective, randomized, single-centre, two-arm, open-label study to evaluate the efficacy of Biotherapi®, a two-strain Bacillus probiotic blend, as an adjunctive therapy in the treatment of rheumatoid arthritis.

**Study objectives**

The purpose of the study is to evaluate the effects of BIOTHERAPI-® (Combination of Bacillus Subtilis 1972 and Bacillus Coagulans 1969) on disease activity and functional ability of RA patients when used in combination with pharmacological anti-rheumatic medications.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 26/02/2018, Institutional Ethics Committee-YAMER (Yashoda Hospital, Behind Hari Hara Kala Bhavan, S.P.Road, Secunderabad –500 003, Telangana State, India; +91 (0)40-67778999 Extn: 8457; no email provided), ref: RP/02/2017

## **Study design**

Single centre interventional randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rheumatoid arthritis

## **Interventions**

Patients with rheumatoid arthritis were randomized 1:1 into two groups.

Patients in the intervention group received adjunctive probiotic supplement (capsules) for rheumatoid arthritis, and patients in the nonintervention group (n=125) received only the standard of care treatment.

Every alternate patient received adjunctive probiotic as per protocol. Each probiotic capsule contained not less than (NLT) 5 billion colony-forming units (CFUs) of *B. subtilis* (SNZ 1972) and *B. coagulans* (SNZ 1969). The standard of care treatment consisted of methotrexate, hydroxychloroquine, sulphasalazine, leflunomide, and methylprednisolone. One capsule of the probiotic supplement was self-administered twice-daily for a period of 90 days (3 months). On-going medication and/or additional therapy such as physiotherapy were allowed.

Patients were observed at two follow-up visits after randomization over the course of 90 days on days 45 and 90.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Disease Activity Score-28-Erythrocyte Sedimentation rate (DAS-28-ESR) measured by blood test at baseline, day 45, and day 90

## **Key secondary outcome(s)**

At baseline, day 45, and day 90:

Symptoms of RA measured using:

1. Clinical disease activity index (CDAI)
2. Tender joint count (TJC)
3. Swollen joint count (SJC)
4. Patient general assessment score
5. Physician Global Assessment of Disease Activity Score
6. General health measured using the Health assessment questionnaire (HAQ) score

**Completion date**

21/07/2019

## Eligibility

**Key inclusion criteria**

1. Between the age of 18 to 75
2. Clinically diagnosed with RA (according to ACR 2010 criteria)
3. Active disease defined by DAS28ESR >2.6
4. On RA treatment for at least 3 months and are expected to stay on stable dose throughout the study duration (i.e ongoing medication and/or other therapy such as physiotherapy are permitted, except immunotherapy)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

250

**Key exclusion criteria**

1. Chronic renal failure/renal tubular acidosis
2. Pancreatitis
3. Inflammatory bowel disease or leaky gut
4. Currently consuming Probiotics with refusal to have a 2 week washout period, known to have allergies to the study product
5. Planned to have surgery during the time of the study
6. Mental illness impairing ability to comply with study
7. Women who are pregnant or plan to get pregnant during the study period, women who are breastfeeding
8. Any illness that could impair their ability to comply with the study, or were enrolled in another study
9. Exposure to >10mg/day of Prednisolone
10. Plan to start with biological agents
11. Subjects having arthritis other than Rheumatoid

**Date of first enrolment**

05/03/2018

**Date of final enrolment**

21/04/2019

## **Locations**

**Countries of recruitment**

India

**Study participating centre****Yashoda Hospitals**

Department of Rheumatology

Behind Hari Hara Kala Bhavan

Alexander Road

Secunderabad

India

500003

## **Sponsor information**

**Organisation**

Yashoda Hospitals

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/10/2020	22/07/2021	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version V0	01/10/2020	08/10/2020	No	No