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

Submission date
29/09/2020

Recruitment status
No longer recruiting

Registration date
02/10/2020

Overall study status
Completed

Last Edited
22/07/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures

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

Overall study start date
23/08/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250

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
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Sponsor information

Organisation
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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2021

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?
Protocol file	version V0	01/10/2020	08/10/2020	No	No
Results article		15/10/2020	22/07/2021	Yes	No