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Randomized controlled trial of a postbiotic's ability to affect microbiome diversity and composition

Submission date
09/04/2021

Recruitment status
No longer recruiting

Registration date
14/09/2021

Overall study status
Completed

Last Edited
06/01/2026

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The bacteria living in the gut (the gut microbiome) can be damaged by antibiotics that are prescribed to cure an infection elsewhere in the body. This can lead to a loss of the diversity of bacteria in the microbiome. To prevent this is an open challenge. The aim of this study is to find out whether a postbiotic supplement, PBPGP22, can increase bacteria diversity in patients at the end of their antibiotic course.

Who can participate?
Otherwise healthy adults who are prescribed antibiotics for a course of 5 days or longer for non-gut related infections

What does the study involve?
Participants are randomly allocated to take alongside their prescribed antibiotic a commercial probiotic and either a placebo control (dummy supplement) or a postbiotic. All patients are asked to take a stool sample with an easy-to-use self-collection kit on 5 days at the end of their antibiotic course.

What are the possible benefits and risks of participating?
The supplement may prevent antibiotic-induced damage to the gut microbiome. This may prevent inflammation, diarrhea, and other antibiotic side effects and complications. All ingredients are currently sold in the US. There is a minimal risk of allergy or adverse reaction. Fermented plant materials and probiotics have the potential for some to cause bloating or gas, an upset stomach or loose stools. The supplements used in this study have not been FDA approved. The individual ingredients have not been shown to interfere with the antibiotics prescribed, but their combination has not been tested, therefore some unknowns exist. Although the researchers will do their best to protect participants study information, there is still a very small risk of loss of privacy.

Where is the study run from?
Baymont Emergency Room (USA)

When is the study starting and how long is it expected to run for?
January 2018 to May 2019

Who is funding the study?
Postbiotics Plus Research LLC (USA)

Who is the main contact?
Aubrey Levitt
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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
IRB#: 120180088

Study information

Scientific Title
Randomized controlled trial of PBP-GP-22 to affect microbiome composition

Acronym
PBP-GP22

Study objectives
It is hypothesized that GP-22 taken daily during a course of prescribed oral antibiotics will increase the bacterial diversity of the gut microbiome at the end of the antibiotic course.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2018, New England Institutional Review Board (197 First Avenue, Suite 250, Needham, MA 02494, USA; +1 (0)617 243 3924; info@neirb.com), ref: IRB#: 120180088

Study design
Randomized controlled single-site double-blind interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gut microbiome diversity loss in patients who receive antibiotics

Interventions
Patients are asked to take one capsule per day of PBPGP22 or a placebo alongside their prescribed antibiotic for approximately 20 days (variability arises because the intervention is given alongside a prescribed antibiotic treatment which may vary in length, intervention from the first day of the antibiotic course and until 10 days after course of antibiotics is completed).

Patients are asked to take stool samples on 5 days relative to their scheduled final day of taking the antibiotic: on their final day of taking antibiotics, the following 3 days, and on day 10 after finishing the antibiotic course. The study kit thus contains five stool sample kits with instructions, 30 GP-22 capsules or 30 placebo capsules (gelatin containing microcrystalline cellulose, identical in appearance). In addition, patients also take a daily capsule of an OTC probiotic during the trial which is included in the study kit. The study kit is barcoded but otherwise unmarked. Study kits were randomized at assembly: a random number was drawn by a computer program to assign treatment (T) or control (C).

An eligible patient who is prescribed an oral antibiotic is asked to participate by the doctor on site. If a patient chooses to participate, a staff member of the clinic or a company representative chooses an unmarked box (the study kit). The staff member or the company representative will not know the treatment arm during the handover of the study kit.

Patients send their samples by post or hand over the samples in person at the study site. Samples are submitted to a research partner for DNA sequencing. The bar codes will allow the sponsor to identify the treatment arm at the end of the trial.

Statistical analyses are included in the IRB. Briefly, diversity at the end of the antibiotic course is compared between T and C at each time point and by using time series analysis methods to compare the diversity trajectory between T and C on the first three timepoints.

Intervention Type
Supplement

Primary outcome(s)

Bacterial alpha diversity measured by 16S rRNA gene sequencing of DNA in stool samples collected at three timepoints relative to the antibiotic treatment course and quantified by the inverse Simpson diversity index: on the final day of antibiotics, the first day after completing the antibiotics course, and the second day after completing the antibiotics course

Key secondary outcome(s))
1. Bacterial alpha diversity measured by 16S rRNA gene sequencing of DNA in stool samples collected at three timepoints relative to the antibiotic treatment course and quantified by the Shannon diversity index: on the final day of antibiotics, the first day after completing the antibiotics course, and the second day after completing the antibiotics course
2. Bacterial alpha diversity measured by 16S rRNA gene sequencing of DNA in stool samples collected at two timepoints relative to the antibiotic treatment course and quantified by the inverse Simpson diversity index: on the third and tenth day after completing the antibiotics course
3. Blood inflammation markers measured using C-reactive protein test at the end of antibiotic treatment course

Completion date
16/05/2019

Eligibility

Key inclusion criteria
1. Otherwise healthy adults with a body mass index (BMI) (18-28 kg/m²)
2. Patients prescribed a course of antibiotics for 5 days or longer
3. Patients have not had another course of antibiotics in the past 6 months
4. Patients are willing to cease taking any other supplements or probiotics

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
32

Key exclusion criteria

1. History of regular and severe constipation, diarrhea, inflammatory bowel disorder or Crohn’s disease
2. Usually experience severe diarrhea (e.g. for more than 3 days) following antibiotic treatment
3. Have a compromised immune system
4. Are taking any immune modulators
5. Have an autoimmune disorder
6. Are diabetic
7. Are taking blood pressure medication
8. Have allergies to the ingredients of T or C
9. Are pregnant
10. Are nursing

Date of first enrolment
17/05/2018

Date of final enrolment
16/06/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Baymont Emergency Room, LLC, Patients Emergency Room
10133 Interstate 10 East
Baytown, Texas
United States of America
77523

Sponsor information

Organisation
Postbiotics Plus Research LLC

Funder(s)

Funder type
Industry

Funder Name
Postbiotics Plus Research LLC

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Aubrey Levitt (aubrey@postbioticsplus.com). Data to be shared: longitudinal bacterial alpha diversity measures (inverse Simpson, Shannon), raw sequencing reads (FASTQ), anonymized metadata (treatment class, i.e. treatment or placebo control), timepoint relative to antibiotic treatment course. Data are available upon publication of the trial results for 5 years by downloading from a sequencing repository such as the sequencing reads archive (SRA). Access criteria: public de-identified data. No restrictions on analyses. Consent was obtained from all participants. Data is completely de-identified such that no Personally Identifiable Information (PII) is included in any datasets.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2025	06/01/2026	Yes	No
Participant information sheet			02/09/2021	No	Yes
Protocol file	version 2		16/09/2025	No	No