ISRCTN11358769 https://doi.org/10.1186/ISRCTN11358769

The effects on asthma of dietary supplements that induce the growth or activity of beneficial microorganisms.

Submission date 27/03/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/04/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/04/2019	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is an inflammatory disorder that causes the narrowing of airways, increased production of mucus and therefore difficulty breathing. Asthma sufferers may experience shortness of breath, wheezing, tightness of the chest and a dry irritating cough. Asthma is a common condition that affects approximately 300 million people worldwide, in the UK 5.4 million people are currently recieving treatment. The NHS spend up to £1 billion a year for the care and treatment of those who have asthma.

This study will investigate how prebiotic supplementation affects asthma, by observing changes in quality of life, use of current medication and inflammation. Prebiotics are a carbohydrate that feed the 'good bacteria' in the gut, otherwise known as Probiotics. These bacteria have an important role in look after our immune system and a reduced number/activity of these 'good bacteria' may lead to development of asthma or increased severity of asthma. This study aims to increase our understanding of how the gut bacteria may affect asthma and the results may lead to a better understanding of the factors that might influence asthma and how these can be managed by targeting the diet.

Who can participate?
Adults diagnosed with asthma

What does the study involve?
Participants are randomly allocated into one of two groups. Group one are given a prebiotc supplement, known as B-GOS. Group two are given a placebo (dummy pill). Both groups will take the supplement, B-GOS, or placebo for 3 weeks. After this time, participants will continue as normal for two weeks, followed by another 3 weeks with either the placebo or B-GOS. Each participant will attend the laboratory for a lung function test, blood sample and to fill out questionnare before the start of each treatment; a total of 4 times over 8 weeks.

What are the possible benefits and risks of participating?
Participants may benefit from gaining a wider understanding into managing and controlling their asthma. Potential risks include possible discomfort when taking blood samples.

Where is the study located?
Nottingham Trent University, Clifton Campus (UK)

When does the study start and end?
June 2019 to June 2020

Who is the main contact.
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253339

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS Application: 253339

Study information

Scientific Title
The effects of Prebiotic Supplementation on Quality of Life, Control of Asthma, and Markers of Systemic Inflammation in Adults with Asthma. A Double-Blind, Placebo-Controlled, Crossover Trial.

Acronym
PSA

Study objectives
Prebiotic supplementation will lead to significant changes in pro-inflammatory/anti-inflammatory markers in the blood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 104 8104; NRESCommittee.EastMidlands-Nottingham1@nhs.net), ref: 19/EM/0088

Study design
Single centre double-blind placebo-controlled intervention crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Asthma, steps 1-4 according to the Birtish Thoracic Society Guidelines (BTS)

Interventions
Block randomisation will be used to randomise subjects into equal groups. At baseline, both groups will give a blood sample, undergo lung function tests, complete a 4-day food diary and asthma related questionnaires. The same measurements will be completed following prebiotic or placebo supplementation after 3-weeks. The measurements will then be completed again following a 2-week washout period. Groups will then crossover research arms and continue a 3

week supplementation period with either the prebiotic or placebo, before the final measurement. Supplements will be randomised by an independent party into 'X' and 'Y', ensuring the study is double blind.

Blood samples will be analysed using flow cytometry and mass spectrometry to observe specific and general changes in protein expression.

Intervention Type
Supplement

Primary outcome measure
Changes in FOXP3 expression by regulatory T cells in adults with asthma, following a prebiotic intervention crossover trial. Measured using flow cytometry at 4 timepoints as aforementioned, baseline, prebiotic, washout and placebo.

Secondary outcome measures
1. Changes in asthma control, and frequency of reliever medication in adults with asthma following prebiotic supplementation. Measured at 4 time points, baseline, prebiotic, washout and placebo; using the Asthma Control Questionnaire.
2. Changes in perception of asthma control (e.g. reduced frequency/severity of symptoms) following prebiotic supplementation. Measured at 4 time points, baseline, prebiotic, washout and placebo; using the Asthma Control Test.
3. Changes in quality of life following prebiotic supplementation. Measured at 4 time points, baseline, prebiotic, washout and placebo; using the Asthma Quality of Life Questionnaire

Overall study start date
22/08/2018

Completion date
24/06/2020

Eligibility

Key inclusion criteria
1.18-50 years of age at the date of your first visit.
2. Body mass index (BMI) of 18.5-25 kg·m2 (we can work this out for you using your height and body weight).
3. Non-smoker.
4. Asthma is defined as Steps 1 to 4 based on British Thoracic Society guidelines.
5. On a stable asthma treatment for 3 months
6. Current medication prescription from your GP if diagnosed with asthma (e.g. maintenance and reliever inhalers).
7. Be able and willing to follow all trial requirements.
8. Disclose any nutritional supplements you take to the researcher, to determine whether these may be considered as ‘exclusion criteria’.

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
14

Key exclusion criteria
1. Suffer from asthma but do not have a current medication prescription from your GP (e.g. maintenance and reliever inhalers).
2. Regularly consume Omega-3 supplements, and/or eat high levels of Omega-3 (e.g. more than 1-2 portions of oily fish such as salmon or mackerel a week).
3. Take aspirin or other non-steroidal anti-inflammatory drugs such as ibuprofen once a day on 5 of of the 7 days of the week.
4. Pregnant or planning a pregnancy during the time of the study (on each visit you will be asked to complete a pregnancy test if you are within childbearing age).
5. Consumed prebiotics and/or probiotics (supplements), drugs that affect gastrointestinal mobility or laxatives in the 4 weeks before signing the consent form.
6. Daily dose of anti-histamine, which you could not temporarily avoid for 72 hours before each testing session without exacerbation of symptoms.
7. Vegetarian or vegan diet.
8. Previously diagnosed with chronic obstructive pulmonary disease (COPD), emphysema, chronic bronchitis, or similar respiratory (breathing-related) illness.
9. Admitted to hospital during the past 12 months for your asthma.
10. History of heart failure, pulmonary hypertension, embolism, or other pulmonary heart disease.
11. History of recurrent chest infections.
12. Acute infection in the last four weeks, and/or major operation in the past four months.
13. History of gastrointestinal drug reaction.
14. Taken antibiotics in the past 3 months.
15. History or current evidence of gastrointestinal disease (e.g. chronic constipation, diarrhoea, irritable bowel syndrome, Chrohn’s disease).
16. Recently taken part in other research projects. Please notify the chief investigator.
17. Lactose intolerant.
18. Regularly take antioxidant supplements, such as beta-carotene, vitamin A, vitamin C, vitamin E, lutein and selenium. Standard multivitamin and mineral supplements are acceptable; however, If a single antioxidant supplement (e.g. Vitamin C), is more than the recommended daily DRV’s this must be checked with the chief investigator.

Date of first enrolment
24/06/2019

Date of final enrolment
24/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
Nottingham Trent University

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Sponsor type
University/education

ROR
https://ror.org/04xyxjd90

Funder(s)

Funder type
University/education

Funder Name
Nottingham Trent University

Alternative Name(s)
NTU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Following study completion, it is planned the results will be published in 2021 in a high-impact peer-reviewed journal

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No