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The effects of a prebiotic supplement on exercise induced asthma and markers of airway inflammation

Submission date
04/01/2016

Recruitment status
No longer recruiting

Registration date
06/01/2016

Overall study status
Completed

Last Edited
27/02/2018

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a common long-term condition that affects approximately 235 million people worldwide. It can cause coughing, wheezing, tightness of the chest and breathlessness. It is caused by inflammation of the small tubes that carry air in and out of the lungs (the bronchi). When a sufferer comes across something that then irritates their lungs (a trigger), the airways narrow causing the symptoms of the disease. Common asthma triggers include allergies (to for example, house dust mites or animal fur) and viral infections. Exercise-induced asthma occurs when the airways narrow during and/or after exercise. It is referred to as exercise-induced bronchoconstriction (EIB). It is very common in asthma sufferers and sports men and women. Asthma can be well-controlled with treatments such as inhaled corticosteroids and short- and long-acting Beta2-agonists. However, these therapies do not cure the condition or prevent disease progression. Many patients also don't take the treatment as they should. Treatments that help prevent the inflammation of the bronchi and the immune response to triggers, without causing harmful side effects, would therefore be of benefit. There is evidence to suggest that the gut microbiota (trillions of live bacteria that live in the gut) has a substantial influence on the immune system and the allergic reaction. Prebiotics have been shown to increase the growth and /or activity of beneficial bacteria in the gut and thereby may protect against and reduce the severity of allergic, and airway inflammatory diseases. Prebiotic Bimuno-galactooliogsaccharides (B-GOS) are especially potent in selectively increasing the growth and/or activity of bifidobacteria (a common beneficial bacteria found in the gut). The effects of B-GOS on asthma in humans, however, is not known. Therefore, the aim of this study was to see if prebiotic supplementation in adults with exercise-induced asthma would reduce the severity of bronchoconstriction (narrowing of the airways) and whether it also helps reduce inflammation of the airways.

Who can participate?
Adults either diagnosed with asthma, or known not to have asthma.

What does the study involve?
All participants (whether asthma sufferers or not) are randomly allocated into one of two

groups. Those in group 1 are given B-GOS to take every day for 3 weeks (21 days). Those in group 2 are given a placebo (a dummy pill) to take every day for three weeks. All participants then resume their normal diet for two weeks before taking the other treatment for an additional 21 days (this means that all participants eventually take both treatments).Each participant attends a laboratory for lung function tests and blood samples to test for evidence of airway inflammation before they start each treatment and then 21 days later (when that treatment ends).

What are the possible benefits and risks of participating?
Participants may benefit from gaining a greater understanding into managing and controlling their asthma and exercise induced asthma. Risks include some discomfort when taking blood samples, and some participants might find that the tests trigger off their asthma symptoms. All asthmatic participants will have their own clinically prescribed medication (β2-agonist) for treating episodes of asthma and EIB.

Where is the study run from?
Nottingham Trent University (UK)

When is study starting and how long is it expected to run for?
December 2012 to March 2014.

Who is funding the study?
Nottingham Trent University (UK)

Who is the main contact?
Dr Neil Williams
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effects of a prebiotic galactooligosaccharide mixture (B-GOS) on the severity of hyperpnea-induced bronchoconstriction and airway inflammation in adults with asthma

Study objectives
It is hypothesised that a prebiotic galacto-oligosaccharide mixture (B-GOS) will reduce the severity of hyperpnea-induced bronchoconstriction and airway inflammation in adults with asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Trent University Human Ethics Committee, 27/11/2012, ref: 229

Study design
Single centre randomised double-blind placebo-controlled cross-over controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Exercise induced asthma

Interventions
Participants were randomly assigned to receive 5.5 g.day of either galactooligosaccharide B-GOS (Bimuno) or placebo (maltodextrin) (Clasado Ltd, Milton Keynes, UK) for 3 weeks.

Participants then followed a 2 week washout period (normal diet) before commencing the alternative supplement for the remaining 3 weeks.

Intervention Type
Supplement

Primary outcome(s)
Pulmonary function data (forced expiratory volume in 1 second, forced vital capacity, and peak expiratory flow) at baseline and in response to the eucapnic voluntary hyperpnoea test (in both asthmatic and non-asthmatic groups).

Data was collected at day 0 and day 21.

Key secondary outcome(s))
1. Baseline and post eucapnic voluntary hyperpnoea (EVH) blood sampling for markers of airway inflammation (chemokines CCL11 and CCL17; tumour necrosis factor-alpha (TNF-α); c-reactive protein; and immunoglobulin E) – (collected in both asthmatic and non-asthmatic groups)
2. Fraction of exhaled nitric oxide (collected in asthmatic group only)

Serum chemokine and TNF-α levels were measured from blood samples taken at baseline and 15 min, 60 min and 24 h after EVH.

Data was collected at day 0 and day 21.

Completion date
03/03/2014

Eligibility

Key inclusion criteria
1. Body mass index (BMI) 20-25 KG.M-2
2. Physically active 3 or more times a week , with each exercise session lasting at least 45 min
3. Non-smoker
4. Non-vegetarian or vegan
5. Asthma sufferers must have own clinically prescribed medication
6. Asthma sufferers must have a GP diagnosis

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Predicted forced expiratory volume in 1 second (FEV1) less than 65%
2. Previously diagnosed with COPD, emphysema, chronic bronchitis or similar respiratory illness
3. Previously admitted to hospital for asthma or other breathing difficulties
4. Asthma exacerbation within the last month (Course of steroids, or hospital visit)
5. History of heart failure, pulmonary hypertension, embolism, or other pulmonary heart disease
6. History of recurrent chest infections
7. Smoker
8. Acute infection within the last four weeks
9. Major operation within the past four months
10. Have a history of taking ω-3 PUFA supplements or supplements with antioxidants above recommended intake, or consume more than three fatty fish meals per week
11. Take a daily dose of aspirin or other NSAIDs
12. Currently taking a daily dose of anti-histamine

13. Currently taking long term asthma maintenance medications – corticosteroids, and leukotriene modifiers that you could not refrain from taking for 4 days prior to laboratory session

Date of first enrolment
02/12/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham Trent University
Nottingham
United Kingdom
NG11 8NS

Sponsor information

Organisation
Nottingham Trent University

ROR
https://ror.org/04xyxjd90

Funder(s)

Funder type
University/education

Funder Name
Nottingham Trent University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes