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The effect of omega-3 polyunsaturated fatty acid dose level on exercise-induced asthma and airway inflammation

Submission date
10/05/2016

Recruitment status
No longer recruiting

Registration date
13/05/2016

Overall study status
Completed

Last Edited
06/07/2018

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Asthma is a common long-term condition that affects about 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 (for example to 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 treatments 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. Subsequently dietary supplementation with omega-3 polyunsaturated fatty acids (ω3-PUFA) eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) has received much interest, but their role in the management of asthma and EIB remains uncertain. Furthermore, very high dose levels of ω3-PUFA have been used in previous research causing issues with cost, compliance and increasing the risk of gastrointestinal discomfort. The aim of this study is to compare a previously used high dose of ω3-PUFA with a lower half dose on pulmonary (lung) function and markers of airway inflammation in physically active asthma patients.

Who can participate?
Adult male patients with asthma or exercise-induced asthma, and adult male healthy volunteers

What does the study involve?
Participants are randomly allocated to take either a high dose of ω3-PUFA, a lower half dose of ω3-PUFA, or a placebo (dummy supplement) in the form of 8 capsules daily for 21 days. There is then a 2-week break before they switch to the second supplement for 21 days, then another 2-week break before they switch to the third supplement for 21 days.

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

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

When is the study starting and how long is it expected to run for?
July 2012 to October 2013

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

Who is the main contact?
Dr Neil Williams

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Protocol serial number
NTU Human Ethics Committee Protocol 187

Study information

Scientific Title
The effect of omega-3 polyunsaturated fatty acid dose level on hyperpnoea-induced bronchoconstriction and markers of airway inflammation in 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, 28/06/2012, ref: 186

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 randomised to a 21-day supplementation of a daily dose of 8 capsules (4 to be taken am, 4 to be taken pm) of either:
1. 6.2 g/day Omega 3 polyunsaturated fatty acid dose (3.7 g EPA and 2.5 g DHA)
2. 3.1 g/day Omega 3 polyunsaturated fatty acid dose (1.8 g EPA and 1.3 g DHA)
3. Placebo (medium chain triglyceride)

Participants followed a 2-week washout period (normal diet) between each supplement condition.

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 of each intervention

Key secondary outcome(s))
1. Fraction of exhaled nitric oxide
2. Urinary concentration of 9alpha, 11beta-PGF2 at baseline and in response to the eucapnic voluntary hyperpnoea test
3. Neutrophil phospholipid fatty acid analysis as a measure of intervention compliance
Data was collected at day 0 and day 21 of each intervention

Completion date
10/10/2013

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)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
20/07/2012

Date of final enrolment
25/01/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Nottingham Trent University
School of Science and Technology
Department of Sport Science
Nottingham
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Sponsor information

Organisation
Nottingham Trent University (UK)

ROR
https://ror.org/04xyxjd90

Funder(s)

Funder type
University/education

Funder Name
Nottingham Trent University (UK)

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?
Results article	results Participant information sheet	01/05/2017		Yes	No

Participant information sheet	11/11/2025	11/11/2025	No	Yes