

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/07/2018	Condition category Respiratory	<input type="checkbox"/> 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 (ω 3-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 ω 3-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 ω 3-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 ω 3-PUFA, a lower half dose of ω 3-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 (β 2-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

Dr Neil Williams

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

Not specified

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

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 measure

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

Secondary outcome measures

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

Overall study start date

28/06/2012

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

Age group

Adult

Sex

Male

Target number of participants

12 asthma patients with 88 exercise-induced asthma patients, and 8 controls with no history of asthma or exercise-induced asthma

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

England

United Kingdom

Study participating centre

Nottingham Trent University

School of Science and Technology

Department of Sport Science

Nottingham

United Kingdom

NG11 8NS

Sponsor information

Organisation

Nottingham Trent University (UK)

Sponsor details

Nottingham Trent University

Department of Sport Science

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Clifton Campus

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Sponsor type

University/education

ROR

<https://ror.org/04xyxjd90>

Funder(s)

Funder type

University/education

Funder Name

Nottingham Trent University (UK)

Results and Publications

Publication and dissemination plan

Publication in a peer-reviewed journal

Intention to publish date

01/06/2016

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	01/05/2017		Yes	No