CENTRE FOR HEALTHY LUNGS
LEVEL 2, HUNTER MEDICAL RESEARCH INSTITUTE

Diet, Airway Inflammation and Bronchodilator Response in Asthma
FAB Study (PART 2)

INFORMATION SHEET

We would like to invite you to participate in a study examining how certain foods affect inflammation and bronchodilator response in asthma. This study is being carried out by researchers from Hunter Medical Research Institute and is part of a larger programme looking at diet and asthma.

What is the purpose of the research?
Certain types of food have been shown to cause inflammation in the body. This inflammation may reach the lungs and contribute to asthma symptoms. Our previous studies have shown that different types of food affect the actions of Ventolin, which is a bronchodilator commonly used as a reliever medication in asthma. This study is designed to examine how different types of food reduce the efficacy of different types of reliever medication.

What choice do you have?
Your participation in this study is entirely your choice. Only those people who give their informed consent will be included in the study. Whether or not you decide to participate, your decision will not disadvantage you in any way and will not affect your current nor future management at John Hunter Hospital. If you decide to participate, you can choose to withdraw from the study at any time without giving a reason. If you decide to withdraw from the study, you have the option of withdrawing all data relating to you. An exception to this is in the case of an adverse event, or a serious adverse event, where the data needs to be retained for regulatory reporting. The researchers may withdraw a participant if it is considered in the participant's best interest or it is appropriate to do so for another reason. If this happens, the researchers will explain why and advise you about any follow-up procedures or alternative arrangements as appropriate.

Who can participate in the research?
We are seeking people over 18 years of age, with a body mass index $\geq$30kg/m^2 and a confirmed diagnosis of asthma. If you are: a current smoker, currently taking cholesterol lowering medication, pregnant or breastfeeding or have diabetes, then this study is not suitable for you.

What does the study involve?
If you agree to take part, we will need to check that the study is suitable for you. We will invite you to come into the HMRI clinic for a screening visit. During this visit we will do a brief medical examination, spirometry and a saline challenge to confirm asthma diagnosis and your response to reliever puffer (Ventolin) and an electrocardiogram (ECG) You will need to withhold the use of your asthma medications for 6-24 hours, depending on which medications you use. If we identify any abnormalities this study is not suitable for you. We will advise you of the results, and with your permission, we will forward the information to your GP for follow up. If no abnormalities are identified, we will organise a mutually convenient time for you to do the study.

For this study, you will need to visit the clinical trials unit at HMRI on 4 occasions with a minimum of 1 week between each visit. Each visit will last about 5 hours.

Prior to coming into the clinic, you will need to fast for 12 hours before your visit, and withhold the use of antihistamines and your asthma medications for 6-24 hours, depending on which medications you use.

However, if you feel that your symptoms worsen significantly during this time, you should use your normal medications, and then come to the clinic as planned. The longest you will be asked to fast is 14 hours. If you feel you will be unable to do this, please notify the study staff.

On arrival you will undertake a number of routine clinical tests (see details below) and take a standard asthma inhaler medication: either oxis or atrovent. After this you will be asked to consume a study meal. The study meals consist of approximately 1 cup of cooked potato, mashed with or without cream. After 2 hours you will be given either confectionary (marshmallows and/or white jelly beans, approximately half a cup) or water (250mL). You may drink water at any time throughout the day. The meals you will be asked to consume and the asthma medication you will be given at each visit will be randomly decided. This means the order in which you will receive the study meals and medication will not be the same for all participants. Neither you nor the researcher will choose what study meal and medication you will receive at each visit.

After performing spirometry to test your lung function and a saline challenge/sputum induction, you will be given one of the 2 different reliever medications mentioned above. A blood sample will be collected, and your blood pressure measured. You will then be asked to consume one of the potato study meals. After 2 hours you will be given either water or confectionary (marshmallows or white jelly beans). At the 1, 2 and 3 hour time-points your lung function will be tested. At 4 hours your lung function will be tested again and you will be asked to perform another sputum induction and provide another blood sample. During your first visit an allergy skin prick test will be performed and a total body composition scan using a dual energy x-ray absorptiometry machine.

- Before the meal - Blood test
Spirometry
Saline challenge and combined Sputum Induction
Blood Pressure
- At 1, 2 and 3 hours after the meal - Spirometry
- At 4 hours after the meal - Blood test
Spirometry
Sputum Induction
Blood Pressure

What do the tests involve?

1. Spirometry– Your lung function will be measured by blowing into a spirometer, a machine that measures the amount of air expelled from your lungs. You will be asked to blow into the spirometer until your lungs are empty (approximately 6 seconds).

2. Saline Challenge and combined Sputum Induction- You will be asked to inhale a mist of salty water delivered by a nebuliser. You will be asked to do this for 30 seconds, 1 minute, 2 minutes, and three lots of 4 minutes. A breathing test will be done at the end of each period and you will be asked to produce a specimen of sputum. This is a routine lung test. The test will be stopped at your request or if your breathing test worsens and you will be given a reliever if you develop any problems with your breathing, which immediately relieves constriction of the airways.

3. Blood Tests- Approximately 40mL (2 tablespoons) of blood will be taken from a vein in your forearm at 0 and 4 hours to measure levels of inflammation and fatty acids in your blood.

4. Blood Pressure -Your blood pressure will be measured using an automatic blood pressure monitor.

5. Questionnaires- You will be asked to complete general background, asthma and quality of life questionnaires and a food intake questionnaire. These questionnaires will take approximately 15 minutes to complete.

6. Allergy skin prick test- This test only needs to be completed on one occasion. A small amount of fluid is put on your skin, then tiny pricks are made on the skin at this location (this doesn't break the skin and is not painful). If you are allergic to the fluid, a small itchy lump will occur. This only lasts for an hour or so and if it is annoying we can give you some cream, which will take the itch away.

7. Body composition - Your height, weight and waist circumference will be measured on one occasion. We will also measure your body composition using a dual energy x-ray absorptiometry (DXA) machine. This is a routine procedure that involves the use of very low levels of radiation. You will be asked to lie on a bed underneath a scanning arm that emits low dose X-rays. The test is not painful and takes about 12 minutes.

Risks associated with tests

- The saline challenge test can cause difficulty breathing, coughing, some discomfort in your chest and wheezing. This is brief and responds promptly to reliever medication (ventolin).

- If you are pregnant, intending to become pregnant or breastfeeding, you cannot participate in this study. If at any time you think you may have become pregnant, it is important to let the researchers know immediately.

- The side effects of having blood collected may include bleeding or bruising at the insertion site and possible dizziness and/or fainting. Please advise the research team if you normally feel dizzy or faint when you have blood collected.

This research study also involves exposure to a very small amount of radiation (DXA body composition scan). As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. A DXA scan delivers <0.010 mSv. At this dose, no harmful effects of radiation have been demonstrated and the risk is negligible. The dose of radiation from this test is similar to the dose of naturally occurring background radiation that everyone is exposed to in two days. All radiation exposures will be carried out in accordance with the ARPANSA Code of Practice "Exposure of Humans to Ionizing Radiation for Research Purposes" (RPS8). We would like you to tell us if you have participated in any research studies in the previous 5 years that have involved the use of radiation, as we need to make sure that you do not exceed a safe cumulative level of radiation exposure.

Costs

Participation in this study will not cost you anything. All the food that we require you to eat during the study will be supplied to you. You will not need to pay for parking while attending the HMRI building. Light refreshments including tea, coffee and snacks will be provided by the research staff at the completion of your visit. Participants will be reimbursed for travel and other incidental costs associated with participation in this study.

How will your privacy be protected?

All information is kept strictly confidential and your name will not appear in any reports. Your identity will be limited to authorised staff working on the study. With your permission, we will advise your general practitioner of your participation in this study. All participants are assigned a study number. All

data collected for the purposes of the study will be transcribed into a separate folder and participants will not be able to be identified from these folders

How will the information collected be used?
The results of this study will be collated and communicated to the scientific community. They may also be compared to results from other studies. Individual participants will not be identified in any reports arising from the study.

The results of the study will also be available to you at the completion of the study; however you should be aware that the study may take over a year to complete.
If you have any questions please feel free to contact one of the research team on the numbers listed below.

Further information:
If you have any questions about the study, your results, or your treatment, you can contact:

Prof Lisa Wood	(02) 4042 0147
Dr Bronwyn Berthon	(02) 4042 0116
Miss Cherry Thompson	(02) 4042 0139

We would like to thank you for your interest in this study, even if you decide not to participate.

Complaints about this research

This research has been reviewed and approved by the Hunter New England Human Research Ethics Committee, Reference No: 11/06/15/4.02. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health Network, Hunter new England Human Research Ethics Committee, Hunter New England Health, Locked Bag 1, New Lambton Heights NSW 2305, Phone (02) 49214950, Email HNELHD-HREC@health.nsw.gov.au

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Diet, Airway Inflammation and Bronchodilator Response in Asthma
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Chief Investigator: Professor Lisa Wood Ph 02 4042 0147

CONSENT FORM

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Sheet, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing, but that any samples collected prior to this will be retained.

I consent to complete the questionnaires and I agree to undergo the tests described in the information sheet.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I consent to secure storage of samples collected in this study to be used in future research, subject to approval by the Hunter New England Human Research Ethics Committee.
YES ☐ NO ☐

Participant 's name (printed)_____

Participant's signature _____ Date _____

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