Are there risks and benefits of participating?

The research team pays for all of the tests you have as part of this study, and may provide some of your asthma medications free of charge depending on which group you are in. You will receive optimum asthma management during your pregnancy.

Experienced research staff will collect all samples from you. The side effects of having blood collected may include bleeding or bruising at the injection site and possible dizziness and/or fainting. Please advise the research team if you normally feel dizzy or faint when you have blood collected.

How will your privacy be protected?

Any information you provide for this study will be confidential. Only the research team will have access to your information. We will allocate all participants a study code so that you are not easily identifiable. Samples will be stored with a unique laboratory number and only be accessible to authorised staff working on the project. Details that identify you will be removed when the study is complete.

This information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

What choice do you have?

It's up to you! Participation in this study is entirely voluntary. If you decide not to participate in the study this will not affect the current or future management of your asthma or pregnancy, or health care for your child.

If at a later date you wish to withdraw yourself or your child from the study you are free to do so.

All information is kept strictly confidential, and your name will not appear in any reports. The results of this study will be collated and communicated to the scientific community.

If you decide to withdraw from the study, you have the option of withdrawing all data relating to you and have any samples destroyed. An exception to this is in the case of an adverse event where data needs to be retained for regulatory reporting.

What do you need to do to participate?

If you would like to participate please see the research nurse at the antenatal clinic or phone the study team on 4042 0130.

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

What if I have a complaint about the study?

This research has been approved by the Hunter New England Human Research Ethics Committee of the Hunter New England Local Health District, Reference number 12/10/17/3.04.

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 Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, Ph (02) 4921 4950. Email: hnehrec@hnehealth.nsw.gov.au.

Find us on facebook (www.facebook.com/breathingforlifetrial)

Information Statement for

Breathing for Life Trial

*The **B**reathing for **L**ife **T**rial: A randomised trial of fractional exhaled nitric oxide based management of asthma during pregnancy and its impact on perinatal outcomes and infant and childhood respiratory health.*

Are you pregnant?
Do you have asthma?

Congratulations on your pregnancy!
You are invited to join our research study

Chief Investigator

Professor Peter Gibson, Senior Staff Specialist, Respiratory and Sleep Medicine, John Hunter Hospital and Hunter Medical Research Institute.

Phone: (02) 4042 0143.

Email: peter.gibson@hnehealth.nsw.gov.au

Co-Investigators:

Dr Vanessa Murphy

Prof Michael Hensley

Prof Joerg Mattes

In partnership with our community

HMRI | The University of Newcastle Australia | Hunter New England NSW Health

BLT_InfoPamphletPregnancy_ JHHSiteSpecV6_081215_basedonMASTERVersion4_081215

Why is the research being done?

This study investigates how best to use your asthma medicines during pregnancy and what impact this has on your baby's health.

A simple breath test called FENO (fractional exhaled nitric oxide) may assist doctors in better managing asthma during pregnancy. Using this test may help to decide the right dose of preventer medication you need to maintain control of your asthma.

Controlling your asthma during pregnancy in this way may have additional benefits for your baby's health. This study is investigating the relationship between the management of a mother's asthma and the health of her newborn, infant and child.

Who can participate?

Women between 12 and 22 weeks of pregnancy who :

*** Have a diagnosis of asthma**

*** Use regular asthma medication**

*** Are over 18 years of age**

*** Have had or will have ultrasound dating of pregnancy**

What does the study involve?

An initial study visit which will take 30-60 minutes and you will have up to 6 monthly visits of up to 20 minutes each.

You will be assigned at random (flipping a coin) to one of the management groups.

Group 1: The Asthma Assessment Group

Group 2: The FENO Management Group

With your permission, we will inform your GP/midwife/respiratory specialist that you are participating in the Breathing for Life Trial as well as the results of your initial assessment and treatment recommendation.

At study visits (both groups) we'd like to:

- Ask about the medicine you take for asthma and how often you get sick.
- Measure your lung capacity and the inflammation in your airways. We will use standard breathing tests (spirometry, FENO) which are not harmful to you or your baby.
- Take a blood sample with your permission. 20ml will be collected at your first visit.
- Collect a urine sample to measure oxidative stress (first visit only).
- Request that you bring in a stool sample. (to be included at some sites only)
- Provide you with some education on how to manage your asthma, and how to use your medications.
- Request that you have additional lung function tests known as FOT (forced oscillation technique) and MBW (multibreath washout). These tests will be optional. They are not painful and would take approximately 15 minutes to perform. We may also request that you have these tests when you bring your baby in for their follow-ups after birth. (to be included at some sites only)

If you are assigned to the Asthma Assessment Group you will be required to attend only **one study visit** during your pregnancy. We will assess your asthma and provide education about how to self-manage your asthma. After this, your asthma will be managed as usual by your GP or respiratory specialist. **If you are assigned to the FENO Management Group, your asthma medications will be adjusted according to the result of your FENO breathing test every 2 months.** If you are assigned to this group will be asked to attend 5 or 6 monthly visits during your pregnancy.

We will try to schedule these visits at the same time as your routine antenatal appointments.

At each visit, we will provide you with your medications for the following month, if needed. At the first visit, we will change your preventer medication to an equivalent treatment of Pulmicort or Symbicort.

If you are a smoker, we will request that you complete a short survey about whether you are interested in quitting and what kind of help you would prefer if trying to quit. This should take less than 5 minutes to complete.

After your baby is born we will:

- Access your medical records from John Hunter Hospital and/or details of the birth from the hospital's Obstetric Database. The information we obtain about you and your baby is routinely collected at antenatal visits and during the birth.
- We would also access your child's medical records to obtain information about any hospitalisations they have in the first year of life.
- Collect cord blood from the placenta

We may contact you to arrange follow-up of your child with a Paediatrician (Prof Joerg Mattes) around the ages of:

6 weeks, 6 months, 12 months, 3 years, 6 years

We will seek your written consent for your child to participate in these visits and we will provide separate information about the study visits as they occur.

What if I have an asthma attack during my pregnancy?

- **Follow your action plan**

Seek medical help from your usual doctor.