Treatable Traits for Asthma in Pregnancy (TTAP Study)

INFORMATION FOR PARTICIPANTS

Introduction

Congratulations on your pregnancy!

We would like to invite you to take part in a research study about asthma during pregnancy. It is called 'Treatable Traits for Asthma Management in Pregnancy' or the 'TTAP' study for short. 'Treatable traits' are other medical problems or behaviours that might affect your asthma. They can include things like hayfever symptoms, mental health, weight gain, smoking or how you use your asthma inhaler. This study will look at which 'Treatable Traits' are important in asthma care for pregnant women.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully, and discuss it with others if you wish.

What is the research about?

Asthma is one of the most common diseases in pregnancy. Many women find that their asthma gets worse and they may need to seek medical help for an asthma attack during pregnancy. When asthma is not well controlled it can also cause health problems for baby. This can include being born too early or too small.

We know that some Treatable Traits are common during pregnancy and treating them may help asthma symptoms. However there are other Treatable Traits which might affect asthma during pregnancy that researchers and doctors don't yet know much about. Examples include gestational diabetes (pregnancy diabetes), exercise levels or reflux (heartburn).

We would like to collect information about any Treatable Traits that you may have.. This will help us understand how asthma can be best looked after during pregnancy. When asthma is well controlled during pregnancy, it helps keep both mum and baby healthy.

This is an observational study only, and no changes to your health care will take place. You will still receive your normal level of pregnancy care, and the health of you and your baby will not be affected by participation in our study.

Where is the research being done?

This study is being carried out at 10 hospitals in NSW and Victoria, including John Hunter Hospital. It is being led by researchers and doctors at the University of Newcastle and the Hunter Medical Research Institute, in Newcastle. It is supported by research grant funding from the Australian Government Medical Research Futures Fund.

Who can participate in the research?

This study is suitable for women in *early pregnancy* (12 weeks to less than 17 weeks*)* who:

- Have a diagnosis of asthma from a doctor
- Have had asthma symptoms (cough, wheeze, breathlessness) and / or have taken asthma medication *in the last 12 months*
- Are over 18 years of age

What does the study involve?

The study involves:

- **3 study visits** at your maternity clinic location (John Hunter Hospital) during your pregnancy. (*duration*: 90min).
- **Online surveys** before each study visit (*duratio*n: 20 min per session)
- **A phone call** around 1 month following your baby's birth (*duration*:15 min)

We would also like to look at your health records from this pregnancy and those of your baby. This is the information that is collected at your usual antenatal appointments. (For example: your blood pressure results, blood glucose test results, your baby's birthweight).

The **online questions and surveys** are about your asthma and other health conditions. You can complete the surveys at home, at a time that suits you. The questions /surveys to complete before the first 2 study visits, should take around 20 minutes to do. Around 40

minutes may be needed for the questions / surveys before the 3rd study visit. Most of the questions are multiple choice questions.

The **3 study visits** are about 10 weeks apart. We will try to make these visits on the same day as your standard antenatal visits to John Hunter Hospital. Each visit should take around **90 minutes.**

At each study visit we would like to:

- **Talk to you about your asthma,** including the asthma medicines you take, how often you get sick from asthma, how you use your inhaler (puffer), your asthma triggers, your other medications or supplements and vaccinations.
- **Provide you with an inhaler (puffer) monitor.** This small device fits over your puffer and collects information about your medication use. We will not change your asthma medication or how often you need to take it.
- **Measure your height and weight.** We would like to take some of your body measurements in a device called a BODPOD. This involves standing in the device for a few minutes with fitted clothing (e.g crop top, leggings). The BOPOD looks at the different amounts of muscle and fat in the body – call 'body composition'. This test does not hurt, and there is no risk to you or your baby.
- **Perform some simple breathing tests.** These will measure your how much air your lungs can hold, and if there is inflammation in your airways. One involves a forced exhalation of breath, and two involve taking normal breaths.
- **Take a blood sample.** Around 20mL of blood (around 1 tablespoon) will be taken from a vein in your arm. We will measure nutrients and inflammation in your body.
- **Collect other body samples including urine, cheek swab, hair and stool swab samples.** Urine is used to measure a chemical called cotinine that comes from tobacco smoke. A cheek swab is used to collect cells to analyse gene activity related to inflammation. A snipped hair sample is used to measure amounts of cortisol in your body, which is related to stress. A stool (poo) swab sample is used to study the gut microbiome, the normal organisms living in your intestine. This sample is collected at home by using special swab over used toilet paper. Some of your samples may be stored indefinitely for future research that is approved by an Australian human research ethics committee.
- **Provide you with an activity-measuring device**. This is worn like a watch on your wrist. We will ask you to wear it for 1 week after your visit and fill out a paper or electronic diary about your activity. We will give you a reply-paid envelope to post it back to us, at no cost to you.

- **Talk to you about collecting your genetic material and linking your pregnancy health records at Visit 1.** New information sheets with separate consent forms will be given to you for these. You can ask questions and decide if you want to take part in these parts of the TTAP study.
- At Visit 3, we may ask if you want to do another short survey online (15min) and a recorded interview about what health conditions are important to you during pregnancy. This would be a separate appointment (by video-call if you prefer) and take around 30 minutes. You can ask to have a copy of your interview recording or transcript if you wish.

In the phone call after your baby's birth, we will ask about how your asthma has been since your last visit. We may ask if you are interested in taking part in further research about your asthma after baby's birth, and lung health in your baby.

Participating is your choice

Participation in this study is entirely your choice. You do not have to take part in it.

If you do take part, you can withdraw at any time without having to give a reason. If you decide to withdraw from the study, you can also choose to withdraw all your health information and have any of your samples destroyed. The only case where information needs to be kept is when an unexpected event happens (called an 'adverse event'). This is very unlikely to happen but these records need to be kept for study reporting.

You can still take part in this study, even if you choose not to do everything.

Whatever you decide, please know that your decision will not affect your medical treatment or your relationship with the staff who are caring for you.

What are the risks and benefits of participating?

The TTAP study is designed to be very safe for you and your baby. There is no extra medication or treatment needed as part of this research study. We will not change your usual health care or medications. The risks are similar to those of a normal antenatal or asthma care visit.

Risks

- Blood collection involves some discomfort at the site from which the blood is taken. There is also a risk of some minor bruising at the site, which may last one to two days. In rare cases, a person may feel faint or dizzy. Please let the research team know, if you normally feel dizzy or faint when you have blood collected. Experienced research staff or Pathology staff will collect all samples from you.

- Side effects from spirometry breath-testing could include feeling breathless, dizzy or nauseous. Some people should not do a Spirometry test. Staff will look at your medical records and ask you questions to ensure that this test is ok for you to do.

- One of the surveys that is part of the study visits (called the DASS-21 questionnaire) asks about feelings related to anxiety, stress and depression. This could cause emotional distress. If this happens, we will support you in getting help.

- Test results from this study may identify a new health issue. If this happens, the study staff will pass the results on to the appropriate health care provider to look at. If they think you need any extra care, they will let your normal healthcare providers (doctors, midwives) know.

Benefits

- As part of the study, you will receive some information from trained staff about asthma self-management. This will include how to best use your asthma inhaler, information about the asthma medication you use and written asthma action plans.

- There may be no additional direct benefits to you from this study. We hope that this research study furthers medical knowledge, and improve treatment of asthma in the future.

How will your privacy be protected?

After study enrolment, you will be given a unique participant ID code. This code will be used to label any of your personal information in the study database, and to label any samples we collect. Your name will not be easily associated with the information and samples. Your information will be confidential and only the database custodian (Associate Professor Vanessa Murphy) and authorised members of the research team will have access to it.

Details that identify you will be removed when the study is complete. The study results may be shown at a conference or in a scientific paper, but you will not be named or identifiable.

All study data will be accessed, used and stored in as per Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

Will the study cost you anything?

Participation in this study will not cost you anything. Our research team pays for all of the tests you have as part of this study.

You will be paid for your travel expenses in relation to attending study visits in the form of an e-gift card ($20 per visit) that will be emailed to you after each study visit. You will also be provided with free parking for the duration of your visit. You may receive a small gift/s for your baby at the study visits.

Will I be able to find out about the results of this study?

Yes. The results from this study will be available on our website www. asthmapregnancytoolkit.org.au when the study is completed (after 2026).

Ethics

This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2024/ETH01289.

Governance

The conduct of this research has been **authorised** by the Hunter New England Local Health District to be conducted at the John Hunter Hospital site (2024STE02376).

Complaints about this research:
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, please contact the **HNE Research Office,** Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra

Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number 2024/ETH01289.

Further Information

When you have read this information, one of your research team members will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Kelly Steel on 0438211806.

This information statement is for you to keep.

Thank you for considering this invitation.

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