PARTICIPANT INFORMATION SHEET - Control Group

Study title: Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

Ethics Approval No.: 2022 FULL 11776

Coordinating Investigator: Dr Hannah Jones, Paediatric Neurologist
Address: Paediatric Neuroservices, Starship Children's Health, Level 3, NZCR Building, 3 Ferncroft St, Grafton, Auckland 1142
Contact number: 09 307 4931

You are invited to take part in a research study. Your participation in the study is entirely voluntary. This information sheet provides information about why we are doing the study, and what it would involve for you and your child if you wish to take part. Please ask if there is anything that is not clear to you or if you would like more information. If you require an interpreter, we can organise one for you.

You may wish to discuss the study with a friend or whanau to help you decide whether you would like to participate or not. The research team are available to discuss the study with your whanau if you would like this.

Please indicate below if you would like to discuss the study through an interpreter:

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a New Zealand sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Samoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

Once you understand the study and what is involved, if you would like to take part, please sign the consent form below. If you choose not to take part in the study, you do not need to give a reason, and your decision will not affect the care that you or your child receives. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

Investigators

Dr Hannah Jones, Neurologist, Starship Hospital and Centre for Brain Research
A/Prof Jane Alsweiler, Neonatologist, Auckland City Hospital and University of Auckland
Dr Steven Lamb, Dermatologist, Auckland City Hospital and University of Auckland
Dr Paul Jarrett, Dermatologist, Counties Manukau District Health Board, Auckland
Dr Michelle Wise, Obstetrician, Auckland City Hospital and University of Auckland
Dr Ngaire Anderson, Obstetrician, Waitemata District Health Board, Auckland
Prof Russell Dale, Neurologist, The Children's Hospital at Westmead, University of Sydney

What is the purpose of the study?

Psoriasis is a common inflammatory skin condition that affects 1 – 2 % of people, and up to 10% of women have an autoimmune or inflammatory disease like psoriasis during pregnancy. The purpose of this study is to help us understand whether psoriasis and inflammation in pregnancy affects fetal brain development. Some animal models suggest inflammation in pregnancy influences brain development, but we do not know if this is the case in humans.

We will recruit 100 pregnant women with psoriasis and 100 pregnant women without psoriasis to the study and collect details regarding pregnancy and delivery. We will then assess each child's developmental profile when they are two years old.

Who can take part in this study?

Pregnant women with and without psoriasis. Participants must not have a diagnosis of any autoimmune disease.

As a pregnant woman without psoriasis, you have been invited to take part in the comparison (control) group of the study.

To take part in this study, you must be planning to deliver your baby at an Auckland Hospital (Auckland City Hospital, Middlemore Hospital, North Shore Hospital or Waitakere Hospital) or primary birthing unit.

What does the study involve for me, my child and our family?

The study will involve:

1. Accessing your medical records
   The research team will access your and your infant's medical records to collect data regarding your pregnancy and delivery. We will also review your child's medical records when they are two years old to collect data regarding their health.
2. Completing a study questionnaire

We will give ask you to please complete a 30-minute questionnaire which asks about your general health and wellbeing such as questions about any dietary supplements, mental health and education. We will ask you to please complete a similar questionnaire about your child and family's health and wellbeing when your child is two years old. There is a separate optional questionnaire for your baby's father to complete during your pregnancy and when your child is two years old.

3. A developmental assessment for your child
   We will arrange a one-hour developmental assessment when your child is two years old. The assessment is called the Bayley Scales of Infant and Toddler Development and will be performed by a child therapist or psychologist. We will provide you with a copy of the results of the developmental assessment, and if any areas of concern are raised, we will discuss these with you, inform your GP, and refer your child to your local paediatric service for further assessment and intervention if needed.

Where will this study be held?

If you agree to take part in the study, we will send you a questionnaire electronically or by post to complete and return to us.

When your child is two years old, we will organise for him/her to have a developmental assessment at the University of Auckland, Grafton, Auckland. A travel allowance will be provided.

What are the possible benefits of the study?

The study will have no direct benefits for you but will help in the care of pregnant women with psoriasis and other inflammatory conditions in the future.

What are the possible risks of the study?

This study is an observational study only so you will not be asked to test any treatments.

The study questionnaire asks general questions about anxiety, mood, and any history of trauma. The questionnaire will be coded for your privacy and support services are listed at the end of the questionnaire should you wish to seek support regarding any of the questions raised. The research team will review the answers of the questions and if they raise concern about your or your child's health, we will contact you to offer support and contact your general practitioner (GP), lead maternity carer (LMC) and/or the maternal mental health team as appropriate.

In a small proportion of children, the developmental assessment may detect unexpected developmental difficulties. This may be distressing for his or her parent, but an

appropriately trained clinician will discuss these results with you, and we will refer the child to the local paediatric service for further assessment and intervention if necessary. Early intervention has been shown to improve developmental outcomes so we expect this information will be helpful in the long-term.

What will happen to my child's and my information?

The data collected for the study will be stored against a unique study code. Only the research team will have access to data that identifies you. All study investigators have signed confidentiality agreements with their respective institutions.

Rarely, the research team may contact your lead maternity carer (LMC), general practitioner (GP) and/or a hospital specialist with your identifiable information if there is significant concern about your or your child's health and wellbeing.

Your child's developmental assessment is potentially useful information for his or her care, and we will make this available to your child's general practitioner or hospital specialist according to your preference indicated on the consent form below.

No material that could personally identify you will be used in any reports on this study.

How will my child's and my information be stored and what are the risks to my privacy?

Your child's identifiable developmental assessment will be held on Auckland District Health Board premises. After the study, it will be transferred to the child's medical records if you wish, or transferred to a secure archiving site and stored for at least 10 years after the youngest participant in the study turns 16 years. The data will then be destroyed.

Coded study data will be kept in a secure web application using a University of Auckland platform. The data platform complies with international and national regulatory requirements for electronic data capture systems.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. No material that could personally identify you will be used in any reports on this study.

Cultural Statement

We recognise that knowledge is taonga and the research will be conducted in accordance with the principles of Māori data sovereignty.

Can I access my child's and my information?

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask a member of the research team (details below).

What if something goes wrong?

In the unlikely event that you are injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

Can I change my mind about participating in this study?

Yes. If you decide to withdraw from the study, a copy of your study information can be sent to you on request and your study record will be destroyed from the study files. If your data has already been analysed at the time of withdrawal, the data will remain in the study results, but your data will be excluded from any further analyses.

Will I be informed of the results of the study?

If you would like a copy of the results of the study, please indicate this on the consent form below and we will send you a summary of the study results once the study is completed.

Who is sponsoring the study?

The study sponsor is Auckland District Health Board. The study is funded by the Neurological Foundation.

Where can I get more information about the study?

If you have further questions, concerns or complaints about the study at any stage, please contact the research nurse, Susan Law, susanlaw@adhb.govt.nz or the coordinating investigator, Dr Hannah Jones, at hannahj@adhb.govt.nz, phone 09 307 4931.

If you would like to talk to someone who isn't involved with the study, you may contact an independent health and disability advocate. Please phone 0800 555 050 or email advocacy@advocacy.org.nz. Further information can be found at www.advocacy.org.nz. Alternatively, you may discuss the study with your general practitioner or health professional.

For Māori health support, please contact Rhonda Holloway (Ngāti Rangitihi), Clinical Nurse Specialist - Kaiārahi Nāhi, Starship Child Health. Phone: 021327125; email rhondah@adhb.govt.nz.

You can also contact the health and disability ethics committee (HDEC) that approved this study. Phone 0800 4 ETHIC or email, hdecs@health.govt.nz.

CONSENT FORM - Control Group

Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

Ethics Approval No.: 2022 FULL 11776
Coordinating Investigator: Dr Hannah Jones, Paediatric Neurologist

Please tick to indicate you consent to the following:
(If you need an interpreter, please tell us.)

- I have read, or have had read to me, the information sheet about this study, and I understand what the study involves.

- I have been given sufficient time to consider whether or not my child and I will participate in this study.

- I have had the opportunity to obtain whanau / family support or a friend to help me ask questions and understand the study.

- I am satisfied with the answers I have been given regarding the study

- I understand that I will be given a copy of this consent form and the information sheet to keep.

- I understand that my child and my taking part in this study is voluntary (my choice) and that we may withdraw from the study at any time without this affecting our medical care.

- I agree to my child having a developmental assessment (Bayley Scales of Infant and Toddler Development) at two-years of age, and will try to inform the researchers of any changes to my contact details so that I can be contacted at this time.

- If I decide to withdraw my child and myself from the study, I agree that the information collected about us up to the point when we withdraw from the study may continue to be processed.

- I consent to the research staff collecting and processing information about my child's and my own

health.

- I understand that my child and my participation in this study is confidential and that no material, which could identify either of us personally, will be used in any reports or presentations on this study.

- I know who to contact if I have any questions about the study in general.

- I consent to the research team notifying my Lead Maternity Carer (LMC) and General Practitioner (GP) that my child and I are participating in this study.

- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

• I am aware that the research team may contact my Lead Maternity Carer (LMC), General Practitioner (GP) and/or hospital specialist if the study data raises significant concerns about my or my child's health	YES ☐	NO ☐
• I wish to receive study updates over the course of the study period.	YES ☐	NO ☐
• I wish to receive a summary of the results from the study.	YES ☐	NO ☐

Declaration by the Participant:

I hereby consent to my child and me taking part in this study.

Participant's name: _____

Participant's signature: _____

Date: _____

Contact phone number: _____

Contact email address: _____

Declaration by Member of research team:

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

CONSENT FORM (Child) - Control Group

Maternal Psoriasis and Infant Neurodevelopmental Outcomes (MaPINO) Study

(To be signed after delivery of the child)

- I hereby consent to my child taking part in this study

- I understand that my child's involvement in this study is voluntary and I may withdraw him/her from the study at any time without this affecting their medical care

- I consent to the research staff collecting and processing information about my child's health from questionnaires and review of their medical records

- I understand that my child's participation in this study is confidential and that no material, which could identify them, will be used in any reports or presentations on this study

- If I decide to withdraw my child from the study, I agree that the information collected about them up to the point when I withdraw them from the study may continue to be processed.

- I agree to my child having a developmental assessment at two years of age, and will try to inform the researchers of any changes to my contact details so that I can be contacted at this time.

- I understand that if any concerns are raised regarding my child's development at two years of age, I will be informed and my child will be referred to our local paediatric service for further assessment.

- I know who to contact if I have any questions about the study in general.

- I would like a copy of my child's developmental assessment sent to their general practitioner or hospital specialist to be included in their medical record. YES ☐ NO ☐

Declaration by the Participant:

Child's name: _____

Name of child's legal guardian: _____

Signature of child's legal guardian: _____

Date: _____

Contact phone number: _____

Contact email address: _____

Declaration by Member of research team:

I have given a verbal explanation of the research project to the participant and have answered all the participant's questions.

I believe that the participant's parent/guardian understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____