Participant Information Sheet

Mate Whenua

Lead investigator: Associate Professor Michelle Wise

Ethics committee ref.: 2023 FULL 13189

You are invited to take part in a study comparing two different ways to follow-up after an early medical abortion (EMA). An EMA is a termination of pregnancy, before 10 weeks' gestation, using medication rather than surgery. After an EMA, it is important to confirm the abortion is successful and there is no ongoing pregnancy. This is uncommon - ongoing live pregnancy after EMA is reported to occur 1-2% of the time.

There are two methods of following up after EMA to make sure you are no longer pregnant. Both methods are probably safe and effective, and each has pros and cons. In Aotearoa New Zealand (NZ), some abortion services use a blood test up to 1 week after the abortion, and others use a home urine pregnancy test 3 weeks after. The aim of this project is to find out which method is easier and more acceptable to women and health practitioners, and which is more cost-effective.

Whether or not you take part in this research study is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

We use the kupu (word) wāhine inclusively to refer to women and/or people with a uterus from all cultures.

Whānau, hapū, and iwi are vigilant in offering support through every aspect of lifespan and overall well-being. Prior to the beginning, and long after the end of life, wāhine as whare tangata remain a focal point of mana, respect, and honour. Wairua and hinengaro, as spiritual and mental well-being, are useful descriptions for areas of health which are impacted by EMA and the end of a pregnancy. This is a critical time for coming together and preventing any compromise to mana wāhine and whānau. Mana wāhine and the experience of EMA is important to communicate to health care professionals, as the information will build more effective options for services.

This information will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or health practitioners, however this is not compulsory – your participation can remain confidential if you wish.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you read and understand all pages.

Voluntary Participation and Withdrawal From This Study

Participation in any research project is voluntary (your choice). If you do not wish to take part you don't have to and you will receive usual care. If you decide to take part and later change your mind, you are free to withdraw from the project at any time. For example, if you have already signed the consent form, but then decide you want to have usual follow-up care (whatever your clinic usually does), we can arrange this for you. You can withdraw from the study at any time by speaking to the nurse, midwife or doctor looking after you.

What is the purpose of the study?

EMA is safe and effective; an uncommon but important outcome is ongoing live pregnancy. We think that a self-assessment follow up method after EMA (including a urine pregnancy test) will result in more complete follow up, and will be as safe and effective at detecting continuing pregnancy as comparative blood tests. Answering this important research question will result in a strong recommendation in the NZ abortion clinical guideline, less variation in practice between abortion clinics and achievement of health equity.

How is the study designed?

If you consent to participate, you will be randomly allocated to one of two follow-up methods; you have a 50/50 chance of being in one group or the other. Up to this point, the abortion process will be the same for every wahine in the study. After you are allocated, you will find out which method of follow-up you will receive.

Who can take part in the study?

Any wāhine who presents to one of the participating services, and is requesting EMA before 10 weeks' gestation, is able to participate in the study. If a surgical abortion is preferred or required, or your health practitioner thinks you should have a specific follow up method, you will not be able to participate.

What will my participation in the study involve?

If you are allocated to the self-assessment group, you will receive a low sensitivity urine pregnancy test to take home (sent via courier if participating via telehealth), with instructions to take the test 3 weeks after the EMA and what to do if the test is positive or negative. Information will be provided on how to interpret the test result with a list of symptoms so you can assess whether you are still pregnant or not. As part of a holistic approach (te whare tapa whā) for Māori, the researcher will touch base with you weekly to help support you and your whānau to manage the process. At four weeks after the EMA, they will specifically ask you if

you did the urine pregnancy test or not. If you did not, there will be two reminders by phone, text message or email.

If you are allocated to the blood test group, you will have the 1st blood test done at the start of the EMA. You will then be given a form to do a 2nd blood test 5-7 days later at your nearest lab. The health practitioner will contact you after the 2nd test to explain the results. If the second test is not done, there will be two reminders by phone, text message or email.

For all participants, a questionnaire about your experience will be completed at 4 - 6 weeks after the EMA and at 12 months after the EMA. You can choose to do them electronically/ online, by telephone with the research team, or on paper to be returned by post.

All communication from the research team to the participant will be confidential and carried out via the participants' preferred method (email, phone call, or text message).

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no risks to you participating in the study, compared with the normal EMA process. If you become upset or distressed as a result of your participation, the researcher can arrange for counselling or other appropriate support by staff who are not members of the research team.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You personally may not have any benefit from participating in this study. We will use the study results to develop better processes for wāhine needing EMA in the future.

WILL ANY COSTS BE REIMBURSED?

There will not be any additional costs for you if you participate, compared with the normal process. We will give you a $20 petrol or grocery voucher as a koha for your participation.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, 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.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the researchers and abortion service health practitioners will record information about you and your study participation. This includes the results of any study assessments, such as your blood or urine test result. If needed, information from your clinic or hospital records may also be collected.

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the researchers and abortion service health practitioners will have access to

your identifiable information for the purpose of completing the study. If you agree, we can also notify your own doctor or GP of your participation in the study.

To make sure your personal information remains confidential, information that could identify you will not be included in any data analysis or report generated by the research team. The findings of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Your information will be held securely by the University of Auckland during the study. Your information will be entered into an electronic database, and paper data collection forms transferred to a secure archiving site. All data will be stored for 10 years and then destroyed.

Your de-identified (coded) information may be used for future research related to EMA follow up. You will not be told specifically when future research is undertaken. Your information may also be added to information from other studies, to form much larger sets of data. You will not get reports or other information about future research that is done.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is currently very small but may increase in the future as people find new ways of tracing information.

Rights to Access Your 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. Please ask the research team if you would like to access your results during the study or if you have questions about the collection and use of your information.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your health practitioner or the research team. If you withdraw your consent, your study participation will end, and you will receive usual care. If you agree, we would like to use information that was already collected up until your withdrawal, and information that can be collected from your medical records until the end of the follow-up.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga, we have consulted with Iwi United Engaged Ltd about the collection, ownership, and use of study data. We may also allow Māori organisations to access de-identified study data for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind about participating in the study, please inform the research team at your abortion service. You will be given their contact details when you first consent to participate in the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

If you are interested in the findings of this research project, we can email you a summary if you provide us with your email address on the consent form.

WHO IS FUNDING THE STUDY?

The study is being funding by Health Research Council of New Zealand.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern B Health and Disability Ethics Committee approved this study on 15th June, 2023. HDEC reference: 2023 FULL 13189.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study, you can contact:

Lead Researcher: Associate Professor Michelle Wise, MD MSc FRANZCOG

Department of Obstetrics and Gynaecology, FMHS, University of Auckland

Email: m.wise@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Māori health support, please contact:
Misty Edmonds (RN) Ngai Tuwharetoa, CEO Iwi United Engaged Ltd
Email: misty@iue.net.nz

Stephanie Shankar (RM) Ngati Tuwharetoa, Iwi United Engaged Ltd.
Email: Mareikura_pepi@live.com

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email:	hdecs@health.govt.nz
Phone:	0800 400 569 (Ministry of Health general enquiries)

Consent Form

Mate Whenua

Please state that an interpreter is available on request if these are available.

Please tick to indicate you consent to the following

- I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.
- I have been given sufficient time to consider whether or not to participate in this study.
- I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study (this is your choice, not compulsory)
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I am willing to be randomly assigned to either follow up method.
- I consent to the research staff collecting and processing my information, including my medical records.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- 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 relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.

	Yes	No
• I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	☐	☐
• I wish to receive a summary of the results from the study.	☐	☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

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

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____