Auckland version

Participant Information Sheet

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Study title: **High urate levels in the transition to gout**
A sub-study of The Genetic Causes of Gout in New Zealand

Locality:	The University of Auckland	Ethics committee ref.:	MEC/05/10/130
Lead investigator:	Professor Nicola Dalbeth	Contact phone number:	(09) 373 7599 extn 86138

You are invited to take part in a study assessing risk factors for developing gout in people with high urate levels. Whether or not you take part 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.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you 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 healthcare providers. Feel free to do this.

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

This document is ten pages long, including the Consent Forms. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Gout is caused by the formation of urate crystals in the joints which can cause pain, swelling and damage of the joints. High urate levels are the leading cause of gout, but not everyone with high urate levels will develop gout. Studies have shown that some people with high urate levels have urate crystals in their joints on ultrasound imaging, even though they do not have gout. It is currently unclear why some people with high urate levels develop gout and others do not.

This is a long term study of people with high urate levels which will help us understand which factors, including urate crystals on ultrasound imaging, can predict the development of gout. This will be a big step towards better understanding the cause of gout and might help to come up with a way to prevent the development of gout. Currently there is no recommended treatment for people with high urate levels as many do not go on to develop gout. It's possible that by identifying factors which cause gout, this study may help us to develop and implement early management strategies in people with high urate levels who are at a high risk of getting gout. This has the potential to reduce the rising global prevalence of gout.

This study will be led from Auckland, and will be undertaken internationally with New Zealand study sites in Auckland, Wellington and Christchurch. This study is part of an international collaboration with researchers in the UK, America and Asia with the aim of recruiting over 900 participants world-wide. If you have and queries regarding this study you are welcome to contact Professor Nicola Dalbeth, University of Auckland, Department of Medicine, phone (09) 373 7599 extn 86138.

This study has been approved by the Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to participate in this study because you have high urate levels but have not had any previous symptoms of gout. To participate in this study you must be aged between 18 and 80 years at the time of enrolment. Unfortunately we cannot include people with end-stage kidney disease who are on renal replacement therapy, those who have serious health issues, or those who plan to shift out of the area in the next 5 years.

If you decide to participate, you will be asked to attend a short screening visit and a longer study visit at the Clinical Research Centre at the University of Auckland. The screening visit will take no more than 45 minutes and will involve a blood test. The longer study visit will take up to 2 hours. We may be able to combine the screening visit with the longer visit. A second longer visit will take place 5 years later, or sooner, if you develop gout. At each study visit we will ask you to complete some questions about your health, assess your height and weight, examine your joints for tenderness and swelling, assess your walking, and ask you to provide a urine sample and blood samples to test your urate levels, creatinine (kidney function) and CRP (marker of inflammation).

We will also ask you to provide blood tests to be stored. It is up to you whether you also agree to your blood samples being used to look at DNA, the genetic code material found inside the blood. It has been known for a long time that high urate levels and the development of gout are partly genetic because of certain genes that we inherit from our parents. We want to find out what these genes are, and how they cause the disease. If you wish to participate in the genetic study we will ask you to also complete a separate Genetics Testing Consent Form located at the end of this Information Sheet.

At the study visits we will also perform ultrasound scans of your feet and knees to check for any urate crystals. At the first visit we will also take an x-ray of your feet to check the health of the bones and joints in your feet.

Over the 5 years between your two study visits we will regularly contact you by phone, text, mail or email to check with you whether you have developed any new joint pain or swelling. If you do, we may schedule you in for your second longer study visit earlier, to assess whether or not this pain or swelling is due to gout.

As part of this study, we will ask you whether you agree to providing us with the contact details of a family member and/or close friend(s) that we can contact if you cannot be reached.

With your consent we also may contact your family doctor to review relevant medical records or access your New Zealand Health Information Services records so that we can see how your health has been.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

This study will involve the sampling of blood. A blood sample taken may hurt a little, and some people get a small bruise where the needle goes in. Occasionally the needle hole can become infected, but this is very rare. Most people have no problems. If you ever faint with blood samples or when you see blood, please let the research assistant know beforehand. That way we can be ready for this, and take the sample while you are lying down.

This study involves radiation exposure from a foot x-ray which will take place at the first of the two longer study visits. As part of everyday living, everyone is exposed to a small amount of background radiation that comes from soil, rocks, outer space and within the body itself. The radiation dose you will receive in this study is about the amount that you receive over 1 day from background radiation. This radiation exposure is necessary for us to obtain information about the health of your bones and joints. The risk from this dose is small.

The ultrasound scans involve no radiation exposure. Ultrasound scanning is safe and painless. Sound waves are used to obtain images of your joints. This technology is the same as that used to scan a pregnant woman and has no known side effects.

WHO PAYS FOR THE STUDY?

Participation in this study is free. The costs for the ultrasound scans, blood tests and x-rays will be covered by us.

We will provide you with a travel voucher to assist you with your transport to and from the study visits.

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 ARE MY RIGHTS?

Your participation is entirely voluntary (your choice). You do not have to take part in this study and if you choose not to take part, it will not affect any future care or treatment. If you do agree to take part, you may withdraw from the study at any time without having to give a reason and this will in no way affect your future health care. We will advise your family doctor that you are participating in the study.

We will advise you and your family doctor of any abnormal test results found as part of the study that have implications for future health. This would include results of blood tests, abnormal x-ray findings and the development of gout during the study. If you do develop gout during the study we can offer expert advice to your GP about gout management. At present, it is not recommended that asymptomatic individuals with high urate levels or ultrasound features of crystal deposition receive medication to reduce serum urate levels.

Although you have the right to access information about you collected as part of the study, both you and the researchers you interact with at the study visits will be blinded to the results from the ultrasound scans until the conclusion of the study. This means that neither you nor the researchers will know the results of your ultrasound scans until the study ends. This is necessary to avoid either you or the researchers influencing our assessments, during the study.

Individual results from this study will be confidential, and no material which could personally identify you will be used in any reports on this study. Study records will be confidential and stored securely. It is up to you whether you consent to your de-identified ultrasound images (without your personal details) being used for training or publication purposes by indicating on the relevant section of the Consent Form.

With your consent, a sample of the blood or urine will be stored for up to ten years after the study and may be used to measure other markers of gout or arthritis. These samples will be stored at the laboratory of Professor Tony Merriman at the University of Otago, in a secure freezer. Samples will be accessible by the study investigators and may be used for other gout-related studies with ethical approval. This may involve sending the samples to a laboratory overseas for testing. In this situation, these samples will be disposed of using established guidelines for discarding biohazard waste.

Implications of genetic testing

If you agree to participate in this study, you do not have to agree to your blood sample being used for genetic testing. If you do agree to your blood sample being used for genetic testing, we will ask you to complete an additional Genetics Testing Consent Form (located at the end of this Information Sheet) stating you agree to the storage and testing of your genetic samples.

You have legal rights over any blood samples you do give for research. The researchers are not allowed to sell or export the DNA. The researchers may, however, need to collaborate with overseas researchers to carry out specific gene studies – this would involve sending a small amount of your DNA overseas. This would require Ethics Committee approval and your DNA would still be under the custodianship of Professor Tony Merriman (through a legally binding Material Transfer Agreement, which would require return of your DNA upon completion of the collaboration). The sample can only be used for research related to arthritis. If you change your mind later, just let us know, and we will return your sample. If you die, your family/whānau can also ask for your sample to be returned.

It is important that people who consent to participate in the genetics study are aware of the broader implications of genetic testing. For example, genetic information can be used to assess insurance risk (we stress that in no circumstances will your genetic information from this study

be released to outside parties). If genetic analysis is done on whānau/family there is potential for procedural error that may cause inconsistencies in the family tree. If this is the case then your data will be discarded and no further action taken.

The cultural issues associated with storing your samples and undertaking genetic analysis on them should be discussed with your family/whānau as appropriate. To avoid problems at a later stage, we suggest that your family/whānau is involved with you at all stages of the research. We are happy to meet with you and your whānau/family to discuss the study further at the time that you donate the blood sample, and to discuss the results of your tests.

You may hold beliefs about a sacred and shared value of all or any blood samples removed. The cultural issues associated with sending your samples overseas and storing your blood samples should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.

By-products from DNA preparation are usually disposed of using medical waste contractors by incineration - if you wish an appropriate karakia to be used to dispose of your by-products when the study is concluded, please indicate your wish on the Consent Form. The samples will be stored at The University of Otago in Dunedin.

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

Your study records will be stored securely for 20 years after the study is completed and then destroyed. If you decide to withdraw from the study, you may request that your samples are disposed of.

We are happy to give you information about the progress of the project and about future projects at your request at any time. We will keep you informed of the results of the study. Please note that there may be a delay between your study visit and publication of the results.

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

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

Professor Nicola Dalbeth
Phone: (09) 373 7599 extn 86138
Email: n.dalbeth@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:

Phone: 0800 555 050
Email: advocacy@advocacy.org.nz

For Māori health support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

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

Phone: 0800 400 569
Email: hdecs@moh.govt.nz

Consent Form

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Please read the following carefully before signing and dating this Consent Form

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
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.
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 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 know who to contact if I have any questions about the study in general.
I understand my responsibilities as a study participant.
I understand the compensation provisions in case of injury during the study.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic 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 agree to local laboratory testing of my urate levels, creatinine (kidney function) and CRP (markers of inflammation).
I consent to my GP or current provider being informed about my participation in the study.
I consent to my GP or current provider being informed about any significant abnormal results obtained during the study.

I consent to the research staff collecting and processing my information, including information about my health from my medical records.	Yes ☐	No ☐
I consent to the researchers accessing my New Zealand Health Information Service Records.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I agree to the storage of my blood and urine samples	Yes ☐	No ☐
I agree to my blood and urine samples being sent overseas for testing and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.	Yes ☐	No ☐
I consent to my de-identified ultrasound images being used for training and publication purposes	Yes ☐	No ☐
I agree to providing the contact details of whānau/family or close friends that can be contacted when I cannot be reached.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

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:

Genetics Testing Consent Form

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FACULTY OF MEDICAL AND HEALTH SCIENCES

Please read the following carefully before signing and dating this Consent Form

I have read, or have had read to me in my first language, and I understand the implications for genetic testing as outlined in the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in the genetic testing component of 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.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this Genetic Testing Consent Form and the Information Sheet.		
I understand that taking part in the genetic testing component of this study is voluntary (my choice) and that I may withdraw my genetic samples from the study at any time without this affecting my medical care.		
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 know who to contact if I have any questions about the genetic testing involved in this study.		
I understand my responsibilities as a study participant.		
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.	Yes ☐	No ☐
I agree to the storage of my DNA samples.	Yes ☐	No ☐
I agree to my blood samples being used for laboratory testing done on the DNA (genetic code material).	Yes ☐	No ☐
I agree to my genetic samples being sent overseas for testing if the researchers need to collaborate with overseas researchers to carry out specific gene studies	Yes ☐	No ☐

I wish to have my samples disposed of with appropriate karakia	Yes ☐	No ☐

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: