Participant Information Sheet

Study title: **The EASY-ALLO Study**

Easing the way to achieving target serum urate in people with gout: a non-inferiority strategy trial using an allopurinol dosing model

Sponsor:	**University of Otago**	**Ethics committee ref.:**	**HDEC 2022 FULL 13478**
Lead investigators:	**Professor Lisa Stamp** **Ms Leanne Te Karu** **Professor Nicola Dalbeth**	**Contact phone number:**	**02108496887**

You are invited to take part in a study about the best way to increase allopurinol for treating your gout. 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 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 have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Gout is a common form of arthritis in Aotearoa/New Zealand. High levels of uric acid in the blood are the main cause of gout.

For gout to be controlled blood uric acid levels need to be below 0.36mmol/l. If this target level is achieved over the long term the number of attacks of gout will reduce and stop.

Allopurinol is the most commonly used medication to reduce blood uric acid levels. The current slow increase in allopurinol dose based on monthly blood uric acid levels is considered the gold standard. However, it can be time consuming and labor intensive as there is no single dose that will work for everyone. In this study we are aiming to see if an alternative way to increase allopurinol based on the dose we predict you will need is just as good.

HOW IS THE STUDY DESIGNED?

This study is being conducted in Tāmaki Makaurau/Auckland and Ōtautahi/Christchurch. We aim to recruit 380 people with gout.

Participants will be randomly allocated to one of two allopurinol dosing strategies: nurse-led intensive treat-to-target serum urate dosing with monthly blood test monitoring or protocol-driven dose escalation based on a predicted allopurinol dose.

You will have up to six in person visits over the year and may have phone contact in between these visits. You may also have an interview at the end of the 12 months to help us understand what worked and what did not. At the end of the first 12 months, you will be discharged back to your GP for ongoing gout management. You will also be contacted at 1 and 2 years after your last visit to see how your gout is being managed.

We will be using allopurinol as the medicine to lower your blood uric acid levels. This is a tablet taken once daily. You will be randomly allocated to either the current way of increasing allopurinol with monthly blood tests or the alternative strategy which is more self-directed based on the dose of allopurinol we predict you will need.

WHO CAN TAKE PART IN THE STUDY?

You are invited to participate in this study because you have gout and you are going to start allopurinol or you are already on allopurinol but your uric levels are still high. During the study you will continue all your other usual medications.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

IF you agree to participate in the study,

- You will be asked to fill out questionnaires about your gout (e.g. how old you were when you had your first attack, how many attacks you have had in the last year and whether you have any other medical problems), your attitudes to medicines and the effect of gout on your work and life
- You will be provided with prescriptions for allopurinol and instructions on how to take it. We will also provide you with a plan to prevent gout attacks while you are getting on the right dose of allopurinol, and medications to treat gout attacks if they occur.
- You will be asked to have blood tests. We will test your uric acid, blood count, liver function, kidney function and the levels of allopurinol in your blood. At each visit you will be asked questions such as how many attacks of gout you have had and whether you have had any side effects from allopurinol. We will also ask you to fill in some questionnaires about your medications and your gout.
- If you are attending the Auckland site, we will offer you an ultrasound scan of your knees and feet at the first study visit and after 12 months. This scan is painless and does not involve radiation. The scan will add an extra 15-20 minutes to the study visit. You can still participate in the study if you decide not to have the ultrasound scan.
- If you have an attack of gout we may take some extra blood samples
- With your consent we may also contact your family doctor, review relevant medical records or access your New Zealand Health Information Service Records so we can see how your health has been.
- Some participants will be invited to take part in interviews about their experience at the end of the study

WHAT WILL HAPPEN TO MY BLOOD SAMPLES?

Depending on where you have your blood tests, they will be sent to the public hospital laboratories or to the local community laboratories in Ōtautahi/Christchurch or Tāmaki Makaurau/Auckland.

Some of the blood samples collected during the study will be stored in our secure freezers at the University of Otago, Christchurch or the University of Auckland. They will be labeled with

a unique study number. These will be used for some specific laboratory work examining inflammation in gout. No information that could identify you will be on the labels. Some samples from people recruited in Tāmaki Makaurau/Auckland will be sent to Ōtautahi/Christchurch for specific tests not done in Tāmaki Makaurau/Auckland.

The study does not involve storing DNA (your genetic material). Samples from the study will not be sent out of Aotearoa/New Zealand.

At the end of the study and once the analysis is completed we will destroy your samples. If you wish your samples to be destroyed with karakia we can arrange this.

If you would like to withdraw from the study at any time you can contact the research co-ordinator. Any blood samples or information that have been analysed up to that time will continue to be used.

You may hold beliefs about sacred and shared values of any tissue samples removed and data originating from the tissue. The cultural issues associated with storing your tissue and data should be discussed with your family/whanau as appropriate. If you need cultural support this can be provided. Please let us know and we will arrange this for you or you can ring the number at the bottom of the participant information and consent form. Cultural support is different to knowing more about the study treatments. In these cases we can arrange a primary investigator to come and talk to you and your whānau.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

As with any medications, there are potential treatment side effects. We will provide you with written information about each medication, depending on which treatment you need. We will monitor you closely for any side effects related to the medications.

Allopurinol is worldwide the first line treatment for gout and has been since the 1960's. It has a number of potential side effects (such as rash, fever, nausea, abdominal pain, diarrhoea, abnormal liver and kidney function tests and changes in the blood count). We will be monitoring you frequently for evidence of any side effects. Should you have a side effect it is important that you contact us so we can decide whether we need to stop the medication or reduce the dose.

In particular if you develop fever, rash, or joint aches you should contact the study coordinator, an investigator or seek medical attention.

It is possible that you may experience some bruising and discomfort after a blood sample is taken.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The direct benefits for you are that you will have close follow-up and monitoring of your gout, and your gout treatment will be carefully tailored. Your gout will be managed by a team of gout experts. They will be dedicated to ensure you get the right dose of allopurinol to ensure that your gout attacks stop.

The study will also help us understand the best treatment approaches for other people with gout.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Should you decide not to participate your General Practitioner will be given written advice about how to best manage your gout.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the study doctors/researchers, nurses and other study staff will record information about you and your study participation. This includes the results of any study

assessments and blood tests. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Study staff (to complete study assessments)
- Your GP will be notified of your participation in this study
- Laboratory staff, to process and report your screening and safety tests
- The Sponsor (University of Otago) and other government agencies, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
- The Sponsor (University of Otago), ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor (your GP or specialist), if a study test gives an unexpected result that could be important for your health or well-being. This allows appropriate follow-up to be arranged.

De-identified Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers AND/OR any study information sent to the sponsor. Instead, you will be identified by a unique code. The researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- The research team
- The Sponsor (University of Otago), for the purposes of this study.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information may be used for future research related to arthritis or gout that is unrelated to the current study.

You may not get reports or other information about this future research done using your information.

Security and Storage of Your Information.

Your identifiable information is held at The University of Otago, Christchurch and the University of Auckland during the study. After the study it is transferred to a secure archiving site and stored for up to 10 years after completion of the study and then destroyed. Your coded information will be entered into electronic case report forms. Coded study information will be kept in secure, cloud-based storage for up to 20 years after the study. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g.

making it harder for you to get or keep a job or health insurance) 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 if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the study nurses or doctors.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

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 The Kaitohutohu Rangahau Hauora Māori, Māori Health Research Advisor at The University of Otago, Christchurch about the collection, ownership, and use of study data.

WHO PAYS FOR THE STUDY?

Participation in the study is free. This study is funded by the Health Research Council of New Zealand. You will be provided with a $20 petrol voucher for each visit you are required to make for the study. You will be required to pay the prescription charges for your allopurinol and gout attack medications.

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. If you would like to withdraw from the study at any time you can contact the research co-ordinator. Any blood samples or information that have been analyzed up to that time will continue to be used.

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. If you wish to access the information we collect about you as part of this study we can arrange this.

We will inform you of any new information about adverse or beneficial effects related to the study that becomes available that may have an impact on your health.

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

At the end of the study you will continue your treatment as prescribed by your doctor.

Overall results of the study will be available from the investigators several months after the study has been completed. This may be several years after your involvement in the study.

WHO IS FUNDING THE STUDY?

This study has been funded by the 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 has approved this study.

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:

Name, position	Rachel Murdoch – Research Fellow / Rheumatologist
Telephone number	09 923 4139
Email	rachel.murdoch@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@hdc.org.nz

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

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

For participants in Tāmaki Makaurau/Auckland: If you require Māori cultural support contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 307 4949 ext 29200. State Title of the study (The EASY-ALLO Study) and names of primary investigators (Stamp, Te Karu, Dalbeth)

EASY-ALLO STUDY

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.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I have been given an information sheet about the risks of allopurinol and have had the chance to read it and ask any questions I may have.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	No ☐
I understand that my GP or current provider will be informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	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 have an ultrasound of my joints (Auckland site only)	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

I consent to the use of my data for future related studies	Yes □	No □
I consent to the researchers accessing my New Zealand Health Information service records	Yes □	No □
I consent to being contacted in the future for follow-up studies	Yes □	No □
I wish my samples to be destroyed with 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: