Targeting Tight Control of Gouty Arthritis

Participant Information Sheet - Patient

Effect of tight urate control in gouty arthritis compared to usual care (TICOGA), a randomised clinical trial

You are being invited to take part in a research trial. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Control of gout flares can be achieved by escalating treatment until low target urate levels have been achieved. In practice many patients do not have treatment adjustment guided by urate test results, reflecting the inconvenience of having to attend for tests and doctor's appointments which are currently needed to guide this process. We want to determine if a supported self-management approach can help patients with gout get established onto effective treatment. The self-management approach will involve self-testing of urate levels using a finger prick test, with interpretation of the results and treatment advice being sent through a smart phone application by researchers in NHS Lothian. We are comparing this approach with the usual care that patients with gout receive. We aim to recruit about 125 patients to the study and to look at the number of gout flares over 2 years.

Why have I been invited to take part?

You have been asked to take part because you have been diagnosed with gout, and because you have been recommended to take urate lowering treatment to improve the control of your gout.

Do I have to take part ?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide not to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

We will provide you with this information sheet as either a paper copy or online, and you will have the chance to read and consider participation. You can indicate your interest either verbally, or by completing a reply slip on paper, or online on our study website: GoutSMART | University of Edinburgh. We will need to collect your email and phone number to be able to contact you about your involvement in the study. You will have the chance to ask the research team questions about the trial prior to formally agreeing to enter the study

After at least 24hrs you will be contacted by telephone to confirm your interest in the study, and will be asked a number of screening questions to see if you are suitable to take part. Screening questions can also be completed online on the study website which should take about 5 minutes.

If you wish to take part in the trial then you will need to sign a permission (consent) form either on paper or online through the GoutSMART trial website. Online consent will be stored on a secure server managed by the University of Edinburgh using a REDCap database. Only the TICOGA trial research team will have access to your information. Reading and signing the online consent form should take about 10 minutes. A copy of the consent form is included at the end of this information sheet.

In line with your normal clinical care a treatment plan will be agreed with all potential participants covering the maximum dose of urate lowering treatment to be used, and whether regular treatment of flares is needed to help you get established on treatment. A visit to hospital may be arranged if you require blood tests to determine this treatment plan. If you are not suitable for the trial a summary of the agreed treatment plan will be sent to your GP for implementation. If you are suitable for the trial and agree to take part then you will go on to have a baseline assessment which can be by phone or in person.

Baseline Assessment:
During the baseline assessment you will be asked to sign a consent form indicating that you agree to take part in the study if you have not done so already. Consent will be obtained by one of the doctors or research nurses in the study team. If you have filled in a consent form online, you will be asked that you understand each of the points made in the consent form. You will be asked to complete a questionnaire exploring how gout has affected you, and about any other medical conditions that you have. Where possible we will take this information from the hospital record directly. We aim to complete all questions at your baseline assessment, but if this is not possible you may be sent the remainder of the survey to complete at home, via a secure personal link to the trial database.

You will be asked to install a mobile phone application called GoutSMART onto your smartphone. Everyone taking part in the study will be asked to enter information about gout flares onto the GoutSMART app once a month. You will be allocated to treatment by a process called randomization, which means each patient is put into a treatment group randomly, like flipping a coin. There is a 1 in 2 chance you will be allocated to TREATMENT-TO-TARGET and an equal 1 in 2 chance you will be allocated to USUAL CARE.

If you are allocated to TREATMENT-TO-TARGET you will be shown how to self-administer the urate finger prick test. The phone application will prompt you to perform finger prick tests of urate once every 2 weeks until your urate levels reach a target level of 0.3mmol/l, and you will enter this information into the phone application to form a diary of your urate levels. This information will be reviewed by the study team who will offer advice on your medicine dose directly. Once you have reached the urate target level you will usually be asked to check the finger prick test just once per month. If you are allocated to USUAL CARE then your treatment escalation will be supervised by your GP. You will not be asked to self-test your urate levels routinely.

All participants that are newly starting on treatment will be given an initial medication supply by hospital pharmacy. We expect the baseline visit will last about 1 hour, though there may be some further wait until your medicine is ready to be collected. For patients reviewed by phone a time to come in to pick up your prescription from pharmacy will be arranged, and you may also receive your urate meter if you are allocated to Treatment-To-Target.

Study Reviews
Further reviews will be carried out after 1 year and after 2 years. These may be in person or carried out by phone and should typically last 45 minutes. You will complete a questionnaire exploring how gout has affected you, similar to the baseline assessment. This can be completed at home via a unique survey link, or at the study review visit. You will be asked to perform a urate fingerprick test. If you sustain a flare in between these visits then you will be asked to complete an abbreviated questionnaire by phone or online. The year 2 review marks the end of the trial. During the trial you will be invited to take part in a recorded interview exploring your understanding of gout and gout treatment. The interviews will be conducted face to face in the University of Edinburgh with anonymous transcripts of the interview analysed for key themes. This is voluntary, and you can let us know at any stage if you would rather not take part. If you choose to do so then travel expenses will be provided.

What are the possible benefits of taking part?

You may gain better control of your gout if your urate levels are monitored closely and adjustments to your treatment put in place promptly, however, this approach has not been fully evaluated before and it is possible that there will be no direct benefit to you in taking part. The results of the study will be very important to guide the treatment of other patients with gout in the longer term.

What are the possible disadvantages of taking part?

There are no direct disadvantages to you taking part in the study. All participants receive at least standard care for the management of gout. However, you will be reviewed at the beginning of the study and again at week 52 and week 104 of the study. The first study visit will take about one hour, with the subsequent visits taking about 45 minutes and may be carried out by phone or in person. You will be asked to check a fingerprick test of urate levels at the week 52 and week 104 visits as well as answering questions about your gout and quality of life.

What if there are any problems?

If you have a concern about any aspect of this study please contact our research team Monday to Friday between the hours of 8.00am and 4.00pm on the number 0131 5372717. During all other times please phone the NHS Lothian switchboard on 0131-537 1000 stating your participation in the Gout SMART study and you will be put in touch with the principal investigator of the study Dr Philip Riches.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen if I don't want to carry on with the study

You are free to withdraw from the study at any time. If you decide to withdraw you do not have to give us a reason why. Your decision to withdraw will not affect the standard of any future care that you might require. Your care will be returned to your GP and you will have no further research reviews scheduled. If you decide to withdraw you will be given the option to withdraw from all aspects of the trial including the use of data obtained up to this point.
In the unexpected event that you can no longer communicate your wishes, due to unforeseen circumstances for example a severe stroke, then you will be withdrawn from the study automatically, however we will retain and use the data that you have contributed up until this time point.

What happens when the study is finished?

At the end of the study you will be followed up in the normal way by your local health care provider. It is our intention to let all participants know about the results of the study when the analysis is complete and this will most probably be done within 6-12 months of the study finishing. We hope the results of this trial will guide future gout treatment within the NHS.

In order to evaluate the full heath economic impact of gout we will ask for your permission to contact Public Health Scotland, NHS Lothian primary care pharmacy team or other NHS organisations to enquire about your use of healthcare resources through 'data linkage'. This is when medical information from two or more sources is brought together. Your CHI number, the NHS or hospital number, will be used for this purpose. Because of delays in such information becoming available this will occur after you have completed the study but it will not involve any additional study visits.

What will happen to the samples that I provide

If you need to provide a sample then this will be analysed by NHS Lothian laboratories in line with usual care. After 1 week all samples will be disposed of safely.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. Information that you enter onto your phone will remain held within the phone and might become available to others if your phone is stolen or otherwise hacked.

How will we use information about you?
We will need to use information from you and your medical records for this research project. This information will include your unique hospital number (CHI number), name and contact details as well as information gathered during the trial on your flares and quality of life. The research team will use this information to do the research and regulatory authorities may check your records to make sure that the research is being done properly. Information gathered will be stored securely on computers within the NHS and The University of Edinburgh with access to this information for support staff in the University of Edinburgh limited to non-identifiable information. Once we have finished the study, we will keep some of the data so we can check the results.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and from community pharmacy records at the end of the study, however if you do not want this to happen, tell us and we will stop.

Where can you find out more about how your information is used?
You can find out more about how we use your information by visiting the Health Research Authority website www.hra.nhs.uk/information-about-patients/ with further information included in the leaflet www.hra.nhs.uk/patientdataandresearch . Alternatively please speak to one of the research team by sending an email to the study lead philip.riches@nhs.scot or by ringing us on [0131 537 2717].

What will happen to the results of the study?

The results of this research will be presented at scientific meetings in the UK and overseas and published in medical journals. We will write our reports in a way that no-one can work out that you took part in the study. We hope that this study will lead to a larger study aimed at demonstrating that supported self-management of gout can be implemented within the NHS in large numbers of patients and across different health boards. You will not be entitled to receive any financial benefit from this work, but we will contact all the participants after close of study to let them know the outcome of the study.

Who is organising and funding the research?

The study is being led by Dr Philip Riches, Consultant Rheumatologist at the Rheumatic Diseases Unit at the Western General Hospital Edinburgh and is being co-sponsored by NHS Lothian and the University of Edinburgh. The study has been funded by the NHS Lothian Charity.

Who has reviewed the study?

The Lothian Gout Patient Advisory Group were involved in developing the smart phone application GoutSMART. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. Approval has also been given by NHS Lothian's Caldicott Guardian and Information Governance teams.

Researcher Contact Details

Dr Philip Riches
Rheumatic Diseases Unit
Western General Hospital
Edinburgh EH4 2XU
E-mail: philip.riches@nhs.scot

Independent Contact Details

Prof Stuart H Ralston
Rheumatic Diseases Unit
Western General Hospital
Edinburgh EH4 2XU
E-mail: stuart.ralston@ed.ac.uk

Complaints

If you wish to make a complaint about the study please contact:
Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
E-mail: feedback@nhslothian.scot.nhs.uk
Tel: 0131 536 3370

Participant ID:		Centre ID (if applicable)	

CONSENT FORM

Effect of tight urate control compared to usual care

		Please **initial** box
1.	I confirm that I have read and understand the information sheet (07.08.2025 version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care and/or legal rights being affected.	☐
3.	I give permission for the research team to access my medical records for the purposes of this research study, including my emergency care summary.	☐
4.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and NHS Lothian), from the NHS organisation or other regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.	☐
5.	I give permission for my personal information (including name, telephone number, Community Health Index (CHI) number) to be stored on secure servers within the University of Edinburgh for administration of the study	☐
6.	I agree to give an additional sample of blood if needed to guide treatment changes (about 25mL, the equivalent of 5 teaspoons).	☐
7.	I give permission for the research team to contact me during the course of the trial to take part in recorded interviews exploring my understanding of gout and gout treatment	Yes ☐ No ☐
8.	I give permission for my unique hospital number (CHI number) to be passed to Public Health Scotland, NHS Lothian pharmacy team or other appropriate NHS organisations for the purpose of data linkage, and for my anonymised data being used in future studies	☐
9.	I understand that the results of this study may be used for the future commercial development of gout treatments and that I will not benefit financially from this	☐
10.	I agree to my General Practitioner being informed of my participation in the study	☐
11.	I agree to take part in the above study	☐

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record