PATIENT INFORMATION LEAFLET 2

Percutaneous Nephrolithotomy, Flexible Ureterorenoscopy and Extracorporeal Shockwave Lithotripsy for lower pole kidney stones

PATIENT INFORMATION LEAFLET 2

INVITATION TO TAKE PART

We would like to invite you to take part in a research study related to deciding which treatment is best for your kidney stone. Before you decide whether or not you would like to take part we want to tell you more about the need for the study and what it will involve for patients who take part.

We would be very grateful if you would read this short information sheet. Please feel free to talk to others about the study if you want to and ask your clinical and research teams any questions that you may have or if you would like more information.

BACKGROUND TO THE CONDITION

About 10% (1 in 10) of people across the world get a kidney stone during their life and so it is a very common problem. Kidney stones often cause pain in the loin (middle of the back), visible blood in the urine or urinary infection which makes the person with a stone see their doctor. The stone is then seen on kidney scans and arrangements are then made to see a hospital specialist (Urologist). Sometimes stones don't cause any symptoms but may be found on a scan done for other reasons. The most common place where a kidney stone lodges is in the lowest part of the kidney called the lower pole. If the stone is large (more than a few mm across) and causing symptoms then treatment to get rid of the stone is usually advised by the specialist.

This study will look at two procedures used to get rid of stones in the lower part of the kidney

- Percutaneous nephrolithotomy (PCNL), a keyhole surgical procedure involving a small cut in the skin to remove stones from the kidney. It is generally used for stones larger than 1 cm
- Flexible ureterorenoscopy (FURS), a telescopic procedure to remove the stone without any cuts in the skin. It is generally used for stones measuring less than 2.5 cm.

Although we know that both procedures can be used to safely get rid of lower pole kidney stones we don't know which one is the best both overall and for individual patients with particular circumstances.

WHAT IS THE PURPOSE OF THE STUDY?

In the PUrE study we want to find out which treatments are best overall and for particular types of people and particular types of stone. The results of the study will give patients with kidney stones and the urologists looking after them much more accurate information to help them decide which procedure they should have. Also it will help the NHS make sure that the best treatments are available and that they are used wisely and safely. To do this we have to compare each treatment in a fair way. To make it a fair comparison people who take part have to agree to have their treatment chosen at random. This means that neither you nor your doctor can choose which treatment you will have and so you have to be prepared to have any of the treatments that are suitable for your stone size.

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been asked to think about taking part in the study because you have a kidney stone larger than 1.0 cm and less than 2.5 cm in size. You and your urologist have decided

that it needs to be removed and that this could be done using any of the available procedures depending on stone size.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not to take part. Please take as much time as you feel you need to make this decision. You can use the information in this leaflet to help you decide as well as discussions with family members, friends, your doctors and research staff. You will receive full care for your kidney stone problem whether or not you decide to take part in PUrE.

If you decide to take part we will ask you to sign a consent form confirming your agreement. However, even after you have signed this form, you are still free to change your mind and withdraw at any time and without giving a reason. If you do decide to withdraw from the study you will still get full care for your kidney stone problem

WHAT WILL HAPPEN IF I TAKE PART?

Patients who agree to take part in PUrE will be randomly allocated to either PCNL or FURS.

It is important that the particular treatment given to each person in the study is decided by a computer system. If you decide to take part this means that neither you nor your doctors can decide which treatment you will receive. There is an equal chance you will be given either of the two treatments suitable for the size of your stone.

Group name	Procedure
Ureterorenoscopy (FURS)	• Involves passing a long, thin telescope called a ureteroscope, through your urethra (tube that carries urine from the bladder to the outside of the body) and into your bladder. It is then passed up into your kidney to where the stone is. The surgeon may either try gently to remove the stone using another instrument, or they may use laser energy to break the stone up into small pieces so that it can be passed naturally in your urine. • Day case procedure or may have overnight stay in hospital • Requires general anaesthetic • Operation lasts 60 – 90 minutes • May need a very thin plastic tube (stent) left to help the kidney drain which is then removed as an out-patient after a week or two.
Percutaneous Nephrolithotomy (PCNL)	• The surgeon makes a small cut in the skin of the back. A narrow track is then made directly into the kidney and onto the stone. A rigid metal telescope is then passed down the track and the stone broken up and removed. • Needs you to stay in hospital for 2-4 days • Needs a general anaesthetic • Operation lasts 60 – 120 minutes • A tube will be left to drain the kidney for a few days after the operation and then removed before you go home without needing any further anaesthetic

You will be given more information about the procedure that you are going to have by the clinical team looking after you and will then sign a standard specific consent form for that procedure (separate from study consent form). More detailed information leaflets about the procedures are also available from the clinical and research staff or at: http://www.baus.org.uk/patients/information_leaflets/category/10/stone_procedures

To collect the information we need, everyone in the study will be followed up in exactly the same way for twelve months after you join the study. You will be asked to answer questions about your general health, pain and use of pain killers when you join the study, directly before your procedure and every week up to twelve weeks after the procedure. If you need any other admissions to hospital or other procedures (such as removing a stent) we will ask you to complete a questionnaire at the time and may follow up with a questionnaire a week later. Approximately twelve months after you join the study we will ask you to complete your final questionnaire. You will also have the opportunity to complete a short health status questionnaire at your discretion throughout the duration of the study. The questionnaires will take about five minutes to complete each time. We may send you up to two reminders and will aim to contact you by post, email, telephone and/or text message, taking into account which communication method is best for yourself. As part of the usual care you will receive for your kidney stone you will be asked to come back to an outpatient clinic at your hospital to check how you are getting on. You will have an X-ray or scan of the kidney about two to three months after the procedure to see if the stone has gone, this is also a usual part of care.

On return of your 12 week questionnaire and again after the return of your final questionnaire (sent 12 months after you join the study) we will send you a love2shop high street voucher to thank you for completing the questionnaires. Please let us know if you do not wish to receive these vouchers.

Apart from having the initial treatment chosen for you and filling in the questionnaires, all the care that you receive on the study will be the same as the standard care that is usually given.

The study nurse or doctor involved in the study will also, with your permission, collect information from your NHS records during the twelve months after you join the study.

All the information we collect for the study, including those who withdraw, will be kept securely for a minimum of 10 years. If you withdraw that data we have collected up to that point may still be used in the study.

WHAT WILL HAPPEN NEXT?

If you are happy to take part in the PUrE study you will be asked a series of questions to make sure that your particular circumstances make you suitable for inclusion in the study. If you are suitable, you will be asked to sign a consent form and complete the first questionnaire. Your details will be entered into a computer system and you will be randomly allocated to receive one of the two treatment procedures. The doctors and nurses treating you will not be involved in your procedure allocation and have no control over what treatment you are allocated. Either procedure would be suitable for the treatment of your kidney stone.

WHAT ARE THE POSSIBLE BENEFITS TO ME OF TAKING PART?

You will receive the same health care from your doctors whether or not you choose to participate in the study. You may not benefit personally from taking part in this study but because of the need for the research team to contact you regularly you will have more frequent opportunity to discuss your kidney stone problem.

By taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with kidney stones, perhaps including yourself as people commonly get another stone. The results of the study will help plan effective services offered by the NHS.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no anticipated risks or disadvantages to participating in PUrE. Whichever procedure you are allocated to, your procedure will be performed by a competent and trained urologist. There are risks associated with all procedures and anaesthetics. Steps are always taken to ensure that these risks are minimised. As part of routine care, you will be well informed of potential risks during the standard NHS consent and care arrangements for each of the procedures. All the procedures may fail to get rid of the stone for you which may mean you will need another procedure. This is the same whether or not you take part in the study.

Reported side effects of flexible ureterorenoscopy include:-

Common (greater than 1 in 10)
Mild burning or bleeding on passing urine for short period after procedure, temporary insertion of bladder catheter, insertion of stent (stent may cause pain) and further procedure to remove it.

Occasional (between 1 in 10 and 1 in 50)
Kidney damage or infection requiring treatment.

Uncommon (less than 1 in 50)
Damage to ureter with need for operation, very rarely scarring of ureter requiring further procedures.

Reported side effects of percutaneous nephrolithotomy include:

Common (greater than 1 in 10)
Bleeding on passing urine for a short period of time after the procedure and raised temperature.

Occasional (between 1 in 10 and 1 in 50)
Occasionally the surgeon may need to make more than one insertion.

Uncommon (less than 1 in 50)
Kidney damage or infection needing further treatment and severe kidney bleeding.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

When you complete the study after 12 months, your doctors will continue your care and treatment as standard. If the study is stopped earlier than expected for any reason, you will be told and your continuing care will be arranged.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

If new relevant information or treatments become available during the study the PUrE Study Office staff will get in touch with you to let you know about the choices available to you.

WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study you should ask to speak to the researchers who will answer your questions (contact details of your local study nurse and the PUrE Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or Private Institution). Contact details can be obtained from your local hospital and an independent contact can be found at the end of this information sheet. In addition to this, you may contact the chairman of the PUrE Trial Steering Committee whose details are available from the local or central trial office.

All the procedures and techniques used in the study are already being used in the NHS to treat kidney stones. Your participation in PUrE is therefore only to help us evaluate these procedures and should not involve any additional risk to you over and above the known risks of the treatment that you receive.

However, if you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, University of Aberdeen and NHS Grampian. Sponsor contact details are available through the research team.

As a patient of the NHS if you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

If you become unable or unwilling to continue in PURE we would withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information that is collected about you during the course of the study will be kept strictly confidential and will be held securely in accordance with the Data Protection Act.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for instance, to send you the questionnaires.

If you participate in the study we will tell your GP you are taking part, but only with your permission. We will also ask your GP to contact us if you visit them with any problems that may relate to your kidney stone.

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny if requested by monitors from the sponsors, the Research and Development Department of your local hospital and the Regulatory Authorities whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

Other researchers may wish to access data from this study in the future (this will not include names, addresses or dates of birth, and it is not possible to identify participants from the data). If this is the case, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can withdraw from the study at any time, but you will need to continue attending appointments with your consultant and/or GP in order to have your kidney stones monitored as part of your standard care.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with kidney stones. The results of this study will also be published in scientific journals and presented at scientific meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study has been designed by UK urological medical doctors and researchers. Patients will be recruited at different hospitals throughout the UK. The study is being funded by the UK National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. It is being co-ordinated by The Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered clinical trials unit, at the University of Aberdeen.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed by a NHS Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans, in accordance with the Clinical Trials Regulations. In this case, the reviewing Committee was the North of Scotland Research Ethics Committee who have approved the way we are doing the study.

THANK YOU

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the PUrE study. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

Study Office contact details:

PUrE Study Office
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Local contact details:

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