PATIENT INFORMATION SHEET

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INVITATION TO TAKE PART

You are being invited to take part in a research study related to the treatment of your ureteric stone. Before you decide if you would like 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 and discuss it with relatives, friends and your doctor or nurse if you wish. Please feel free to ask questions if the information is not clear or if you would like more information.

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been chosen because you have been diagnosed with a stone in your ureter (the tube which drains the urine from the kidney to the bladder).

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 read this information sheet as many times as you wish and ask your doctor or research nurse as many questions as you need.

Whether you decide to take part or not you will still receive standard care for your ureteric stone.

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 withdraw at any time and without giving a reason. A decision to withdraw from the study will not affect the standard of care you receive.

BACKGROUND TO THE CONDITION

Ureteric stones are very common; 2-3% of the general population have suffered from this condition. Ureteric stones have been found to have an impact on individual's quality of life due to the severe pain produced which requires prescription of pain killing medicines, admission to hospital and time off work and social activities.

There are a number of different treatments used to get rid of ureteric stones. These include a number of telescopic procedures which remove the stone or else shock wave treatment can be applied from outside the body to break up the stone. In recent years the benefit of drugs to help pass the stone has been tested. These drugs relax the muscle fibres of the ureter and it is thought that this may make the stone come out quicker. Tamsulosin and nifedipine are two different drugs that have this action. These drugs are already in common use to treat other health problems such as high blood pressure or bladder problems. The new use of these drugs to encourage ureteric stones to come out more quickly is known as medical expulsive therapy (MET). It may be that the use of MET can reduce the risk of associated complications present with other treatments.

WHAT IS THE PURPOSE OF THE STUDY?

This study will test whether drug treatment with either nifedipine or tamsulosin will make ureteric stones come out more easily and quickly.

HAVE ANY STUDIES LIKE THIS BEEN DONE BEFORE?

Preliminary studies into the use of MET to treat ureteric stones have been conducted, but these studies had a small number of participants taking part and did not directly compare these medicines with a non-active 'dummy' capsule (placebo). As the benefit of this treatment remains unclear the research authority of the NHS, the National Institute of Health Research, have decided to carry out a comprehensive study. The study is called SUSPEND and it is a large UK wide study that will compare the benefit of nifedipine, tamsulosin and a non-active 'dummy' capsule (placebo) to see whether nifedipine or tamsulosin are worth introducing as standard treatment for people with ureteric stones in the NHS.

HOW WILL WE DO THIS?

Patients who agree to take part in SUSPEND will be randomly allocated to be given one of the following treatments: nifedipine or tamsulosin or placebo (non-active 'dummy' capsule). The particular treatment given to each person in the study will be decided by a computer system (see the table below for the treatment groups). 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 placed into any one of the three treatment groups below. To take part in this study you must be happy to take any one of these treatments for up to 28 days.

Group number	Group name	Treatment
Group 1	Calcium Channel Blocker	Nifedipine (one 30 mg oral capsule each day for up to 28 days)
Group 2	Alpha Blocker	Tamsulosin (one 0.4 mg capsule each day for up to 28 days)
Group 3	Placebo	Placebo (one non-active 'dummy' capsule each day for up to 28 days)

To collect the information we need everyone in the study will be followed up in exactly the same way for a period of 12 weeks after starting the treatment. We will ask you to complete three short questionnaires; one before you start the study, one four weeks after you start and one 12 weeks after you start. The questionnaires will ask you to detail the symptoms you experience due to your ureteric stones and how this affects your day-to-day life. We will send you the questionnaires in the post and may send you a reminder by post or e-mail. If you have a mobile phone we may send you a text message to let you know your questionnaire is on its way.

The study nurse or doctor involved in the study will also collect information from your hospital and family doctor records during the 12 weeks after you join the study.

After your initial hospital visit for your ureteric stone you will be asked to come back to an outpatient clinic at your hospital to check how you are getting on. If your ureteric stone symptoms are still not adequately controlled you may receive further treatment in the same way people with ureteric stones are usually treated. All the

care that you receive on the study will be the same as the standard care that is usually given apart from the capsules you will take as part of the study.

WHAT WILL HAPPEN NEXT?

You will be given time to consider the information given in this sheet and your doctor or nurse will further explain the study and what you need to do if you want to take part. You will have the opportunity to ask the doctor or research nurse as many questions as you need to fully understand your participation in the SUSPEND study.

If you do not wish to take part in the SUSPEND trial you do not have to give a reason and this will not affect the healthcare you will be given.

If you are happy to take part in the SUSPEND 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 three possible study treatments we are testing. Neither you nor the doctors or nurses treating you will know which treatment you are taking. This information will however be known at the study office and can be released to the doctors treating you if needed. You will be given a pack of study medication and asked to take one capsule every day until you pass the stone or until you finish the pack. You will also be given an information leaflet about the medicine and a telephone number to contact in case you have any concerns about the study treatment while you are taking it.

WHAT ARE THE POSSIBLE BENEFITS TO ME OF TAKING PART?

You will receive the same proper health care from your doctors whether or not you choose to participate in the study or not. You may not benefit personally from taking part in this study. There is no guarantee that MET therapy will be successful, however you will be offered other treatment if your symptoms get worse or do not improve.

By taking part in this study you will be directly helping us to inform the treatment of future patients diagnosed with ureteric stones. The results of the study will help plan effective services offered by the NHS.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

The disadvantages of taking part in this study include possible reactions to the study medication which you are randomised to. Some people could have side effects with the medications used in the SUSPEND study, but these are usually mild and disappear after a short while. The medications used are not new drugs and have been in routine use for many years for other health problems.

Side effects that have been reported with these medications include:-

<u>Common (less than 1 in 10, more than 1 in 100)</u>
Dizziness, headache, constipation, abnormal ejaculation.

Uncommon (less than 1 in 100, more than 1 in 1,000)
Rapid heartbeat, palpitations, runny and itchy nose, diarrhoea, nausea, vomiting, indigestion, itching, rash, increased frequency of urination, fainting, mood changes.

Rare (less than 1 in 1,000, more than 1:10,000)\
Feeling of pins and needles, swollen gums, impotence, swelling.

Very Rare (less than 1 in 10,000 or rate unknown)
Feeling of weakness, lethargy, eye pain, shortness of breath, prolonged and painful erection, allergic reactions including swelling of lips face and neck, blurred or impaired vision, nose bleeds, exfoliative dermatitis.

If you decide to participate in the SUSPEND study, you will be provided with an information leaflet with your medicine. Please, read all the information contained in this leaflet about your treatment.

WHAT SHOULD I TELL MY DOCTOR IF I DO DECIDE TO TAKE PART?

Please tell your doctor if you have previously had a reaction to nifedipine or tamsulosin. Please also tell your doctor about other medicines you take, either prescribed or those you buy for yourself including herbal remedies.

If there is a possibility you are pregnant please tell your doctor as you will be required to take a pregnancy test before entering the study. If you are pregnant you cannot take part in the study.

If you are a woman of child bearing potential you will need to use a highly effective form of contraception while you are taking the study medication and for at least 28 days after. Acceptable forms of contraception include:-

- Combined oral contraceptive pill, progesterone only pill (mini-pill), transdermal patch, depot-provera injection or implanon implant.
- Intra-uterine system (Mirena) or device.
- Condom or Occlusive cap (diaphragm or cervical/vault caps) ***plus*** a spermicidal foam/gel/film/cream/suppository.
- Female sterilisation or sole male partner is sterile.

Since no contraceptive method is 100% reliable on its own, we advise the use of additional methods of contraception from the start of the study.

If you require any further advice on contraception during this study please ask.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. However, if you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of the study, University of Aberdeen and NHS Grampian. Contact details for both research sponsors 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 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 SUSPEND 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. In addition to this, you may contact the chairman of the SUSPEND Trial Steering Committee (an experienced, retired doctor who is independent from the study) through the SUSPEND study office.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Your doctor will continue your care and treatment as standard.
In the unlikely event you are unable to continue in SUSPEND we will withdraw you from the study and ask you to stop taking the study medication. Your doctor will continue to treat you as standard. 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.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

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. 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 the study. Data for all participants in the study, including those who withdraw, will be kept for a minimum of 30 years.

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 ureteric stones monitored as part of your standard care.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

If a new treatment or information becomes available during the study, you will be made aware of this and you can decide if you would like to continue taking part. You may decide this at any time and your decision will not affect your long-term care. If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

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 ureteric 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 in England, Wales and Scotland. 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 Fife and Forth Valley Research Ethics Committee who have raised no objections from the point of view of medical ethics. In addition the study has also been reviewed and approved by the Medicines and Healthcare Products Regulatory Agency, the Research & Development department of your local hospital and the study funder (NHS NIHR HTA).

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Aberdeen, NHS Grampian 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.

THANK YOU

Patients and doctors rely increasingly on the results of clinical studies, such as SUSPEND, to make sure they are making the right decisions about treatment. 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 SUSPEND study.

FURTHER INFORMATION AND CONTACT DETAILS

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

Study Office contact details:

SUSPEND Study Office
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
3rd Floor, Health Sciences Building
Foresterhill
Aberdeen AB25 2ZD
Telephone: [redacted]
Email: [redacted]
Website:
[redacted]

Local contact details:

<<Insert contact details of local PI and/or Research Nurse>>