



Female Urgency, Trial of
Urodynamics as Routine Evaluation

FUTURE Study

PATIENT INFORMATION LEAFLET

INVITATION TO TAKE PART

We would like to invite you to take part in a study looking at the role of special bladder tests called **Urodynamics**. These tests are done routinely in many UK hospitals to assess patients who have overactive bladder symptoms (OAB) but have not improved following conservative treatment. The FUTURE study is looking at how useful the tests are in improving this condition.

The study will run for four years and aims to recruit around 1000 patients from over 40 hospitals across the UK. 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 this leaflet carefully. Talk to others, including your GP, about the study if you wish. Ask us if there is anything that is not clear or if you want more information.

WHY HAVE I BEEN INVITED TO TAKE PART

You have been invited to take part in this study because you have a condition called refractory OAB. This has been diagnosed because you have experienced some or all of the following:

- Passing urine more frequently than normal
- A strong desire to pass urine that you find difficult to delay
- Leakage of urine when you can't get to the toilet in time
- Getting up frequently to pass urine through the night

Conservative treatment (such as bladder training, pelvic floor exercises or medications) has not helped and you and your doctor have agreed that you would like to try further treatments.

Before beginning further treatment for your condition, doctors are advised to do a test called **Urodynamics**.

This test involves passing catheters (thin tubes) into the bladder and back passage (rectum) or the vagina. The bladder is then filled with water enabling your clinical team to study how the bladder behaves during different situations and activities. The test aims to find the underlying causes of your symptoms and therefore help your doctors suggest the best treatment for you

However, some patients find the Urodynamics test embarrassing and/or uncomfortable. After the test, some get cystitis (a urine infection). In almost 40% of the patients, the test fails to show the underlying cause of the problem.

Where no cause is found, doctors will suggest treatment based on the patient's symptoms and what they find during examination. Sometimes, they may also use tests like ultrasound scans. Together, this range of assessment is called "comprehensive clinical assessment".

At present, it is unclear if the Urodynamics test gives better outcomes for the patient than comprehensive clinical assessment alone.

WHAT IS THE PURPOSE OF THE STUDY?

The FUTURE study aims to assess whether routinely performing the Urodynamics test improves the outcomes of treatment. We also want to assess whether doing the test on everybody is needed and makes the best use of the NHS resources.

DO I HAVE TO TAKE PART?

No. It is entirely up to you. Take as much time as you need to decide. Study this leaflet and ask your consultant, GP and/or research nurse as many questions as you like.

You can withdraw from the study at any time without giving a reason. If you decide to take part but then want to withdraw, you will be contacted by a member of the research team to find out if there is a specific aspect of the study, or the whole study, that you may wish to withdraw from. 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.

Whether or not you decide to take part in the FUTURE study, you will receive the normal high standard level of NHS care.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part, you will be asked to sign a form giving your consent to be included in the study. You will also be asked to complete a 3-day bladder diary, and fill in an initial questionnaire about your bladder problems and the impact they have on your quality of life. You may be sent this questionnaire by post (or email if you prefer) to complete at in the convenience of your home.

HOW DOES THE STUDY WORK?

Participants in the FUTURE study are split into two groups. One will undergo the Urodynamics test combined with comprehensive clinical assessment. Participants in this group may also receive their local hospital leaflet explaining what the Urodynamics test involves as per the local standard clinical care. The other group will undergo comprehensive clinical assessment only. Whichever group you are in, the diagnosis and the decision for any subsequent treatment you will be offered will be mainly guided by the results of these tests. All the treatments that you will be offered will be in line with the NHS standard clinical care in your hospital.

If you join the study, the decision whether you receive a Urodynamics test or not will be decided at random by a computer. There will be no input from your doctor, or from you. You have an equal chance of being placed in either group.

Follow-up: Taking part in the study will not mean any extra appointments or tests. We will, however, ask you to tell us how things are at three, six and fifteen months after you take part. We will do this by sending you questionnaires asking about your bladder symptoms, how they impact on your quality of life, and your views and experience with the treatment you received. You will be asked to send the questionnaires back to the study office, in the pre-paid envelope provided. It is important that you complete and return the questionnaires even if you are still receiving, or are waiting to receive, treatment for your bladder problems.

When we receive your completed 15 month questionnaire, we will send you a token of appreciation for your help. If you don't want to receive this gift, please let us know on the consent form.

WHAT ARE THE BENEFITS OF TAKING PART?

You may not benefit personally from taking part in the FUTURE study. However, you will be helping clinicians, future patients and decision-makers within the NHS to decide on the most effective way to assess and treat women like you with refractory OAB.

WHAT ARE THE DISADVANTAGES OR RISKS OF TAKING PART?

We do not think that there are any disadvantages to you in taking part in this study, nor do we expect any harm to come to you. Whichever group you are in, your tests and assessments will be performed by competent and trained clinicians.

It is important to remember that there are risks associated with every test or treatment. As part of routine clinical care, you will be informed of any potential risks. Steps are always taken to ensure that these risks are kept to a minimum.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Your doctor will continue your care and treatment in line with NHS standard clinical care in your hospital.

If the study is stopped earlier than expected for any reason, you will be informed and your continuing care will be arranged as per NHS standard clinical care in your hospital.

WHAT IF THERE IS A PROBLEM?

If you believe you have been 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: The University of Aberdeen and NHS Grampian, contact details are available through the research team.

If you believe you have been harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (contact details of your local study nurse and the 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 Procedure. Details can be obtained from your local hospital.

WILL MY DETAILS BE KEPT CONFIDENTIAL?

Yes. All information which 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 for up to 10 years after the study has ended. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords. Personal information, for example, your signed consent form, will be kept separate from your research data. Access to any personal information is restricted to individuals directly involved in the trial.

WHO WILL KNOW I AM TAKING PART?

Certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

With your permission, we will tell your GP that you are taking part. You can indicate on the study consent form if you would prefer your GP not be informed.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and/or the NHS Research & Development Department of your local hospital whose roles it is to check this research is properly conducted and that the interests of those taking part in this study are protected.

FURTHER RESEARCH

A. Interview study:

A further part of the FUTURE study will involve members of the study team asking some of the participants to take part in an interview. The interviews aim to explore the participants' expectations and preferences for the treatments, and their views on the assessments and or tests that they received prior to treatment.

Later in the study, some participants will also be invited to share their views following treatment. The interviews will take no longer than one hour and will either be in person or over the telephone.

The study consent form asks if you are interested to taking part in the interview study. If you are, you may receive a separate information sheet about the interviews, and an additional consent form.

B. Long-term Follow-up:

We aim to apply for further funding and the necessary approvals to carry out longer term follow-up of the women who took part in the study. If we are successful, the follow-up would include postal questionnaires and a review of local medical records and national health registers. This is to find out about any further relevant treatments received and/or hospital re-admissions you needed.

To carry out this follow-up study we would need to send some information about you to national health registers. This information would then be matched to their records about hospital admissions, and then returned to the study office. Any information would be sent and stored securely throughout the process.

You will be asked, on the study consent form, to indicate if you are willing to be contacted for the long-term follow-up.

It is up to you if you would like to take part in this further research. It will not affect any other part of the study.

Other researchers may wish to access data from this study in the future but it will not be possible to identify you because your name, address and date of birth will not be included. The sponsors will ensure that any other researchers comply with legal, data protection and ethical guidelines.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes, during the course of a study, new information becomes available about the investigations that are being

studied. If this happens, and there is an impact on the FUTURE study the study team will contact you. We are currently not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Once the study is completed, the results will be analysed. We expect the results to inform clinicians, patients and decision-makers within the NHS about the best clinical /treatment pathway for women with refractory OAB and the best use of NHS resources.

The results of this study will be published in scientific journals and presented at appropriate meetings. You will not be identified in any publication. 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 STUDY?

This study is sponsored by the University of Aberdeen and NHS Grampian who have overall responsibility for the management of the study. The study is funded by the National Institute of Health Research (NIHR). The research is being carried out by a group of experienced doctors and researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed and approved by The North of Scotland Research Ethics Committee.

Thank you for reading this

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 FUTURE 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:

FUTURE

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Local centre contact details