



SHORT PATIENT INFORMATION LEAFLET

You have been invited to take part in a research study. Before you decide whether you want to take part or not, it is important that you understand why the research is being done and what taking part will involve. This leaflet contains the main things you should know. More information is included in a longer Patient Information Leaflet, which you can request if you feel that you might be interested in taking part.

You are being invited to take part because your bladder problem has not improved since you began treatment and you have agreed that surgery may help. Often at this stage your doctor would arrange some more tests that are thought to help decide whether an operation is the right thing for you, and what type of surgery you should have. But it is not clear whether the tests really help in this decision or whether the decision can be made just as well without them. The tests are called bladder function tests, urodynamics, or cystometry. Because they involve putting a tube (catheter) into the bladder, they are described as 'invasive tests', and because of this they do have some minor risks and complications. We need to be certain whether the benefits gained from having these tests done justify taking these risks. The first part of our research is a 'pilot study'; this tests the methods that we might use in a later larger study, and tells us how many women we will need to include. It is this 'pilot study' that you are invited to take part in.

Do I have to take part?

- No, you do not have to take part. It is your decision. Not taking part will not affect the standard of your care.
- Even if you agree to take part you can change your mind later. You can withdraw from the study at any time.
- If you decide you want to take part, tell the doctor or nurse at the hospital. They will organise it for you.

What will happen if I take part?

In general your care will be very much the same as if you do not take part. A doctor or nurse will talk to you about your symptoms, examine you, and may carry out some basic tests.

You will then be allocated to one of two groups at random (by chance, like flipping a coin). One group will have the urodynamic tests we are studying and the other will not. You will have a 1 in 2 chance of being allocated to either group. There is no advantage to being in one group or another because there is no evidence to prove that one way of doing things is better than the other. If evidence existed then we would not need to do this research. This sort of 'randomised study' is the best way of comparing two methods of doing things in health care.

Apart from the decision to use urodynamic tests or not being made for you at random, there will be no difference in the care you receive whether or not you take part in the study. Whether you have surgery or other treatments, your doctor will decide with you which seems most likely to be your best option and your treatment will proceed as normal.

You will be asked to fill in a number of questionnaires before treatment and again six months afterwards so we can assess how well your treatment has worked. The questions cover what happens to your urinary symptoms and the effect that these symptoms have on the quality of your life and general health.

All information about you will be kept strictly confidential; any details of the study that leave the hospital will have all personal identification removed so nobody will know it is about you.

Where can you find out more?

More detailed information is included in the full Patient Information Leaflet, which can be obtained from the medical or nursing team treating you at the hospital. Also, you can contact your local study team for further information or you can get in touch with the central trial management team in Newcastle. Contact details are given at the end of the full Patient Information Leaflet.