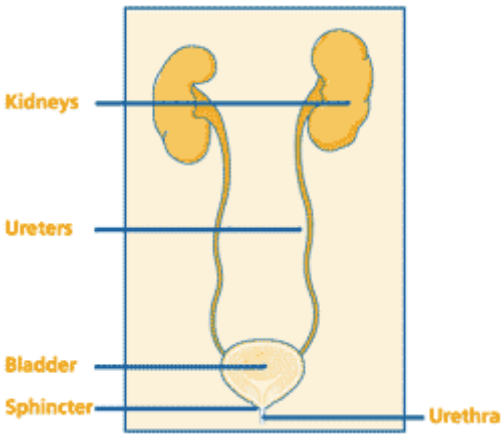
# Patient Information Leaflet

## Invitation to take part

You are being invited to take part in a research study. Before you decide, 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 others if you wish. Ask 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. Thank you for reading this.

## What is the purpose of the study?

Fetal bladder outflow obstruction is a congenital 'blockage' of the tube connecting the bladder neck to the external part of the baby (the urethra).




This may cause permanent damage to the baby's kidneys (probably due to increased pressure) and can lead to poor lung development and physical deformities such as clubfoot.

Over all, about half of babies diagnosed with this problem before birth will die, either before birth or in the new-born period. For several years, treatment to relieve the obstruction (vesico-amniotic shunting) has been offered, but with only weak evidence that it improves survival and kidney function in those treated. We are carrying out a trial comparing no treatment before birth with vesico-amniotic shunting in order to find out if it really does help. If the scans and results of the tests we perform today confirm that your baby is affected, we will ask if you are willing to help us with this trial. This leaflet tells you what it involves.

## Why have I been chosen?

Because the scan appearances today suggest that your baby has bladder or urinary tract outflow obstruction. We estimate that we need to study at least 200 babies affected by this problem to discover if this treatment really helps.

## Do I have to take part?

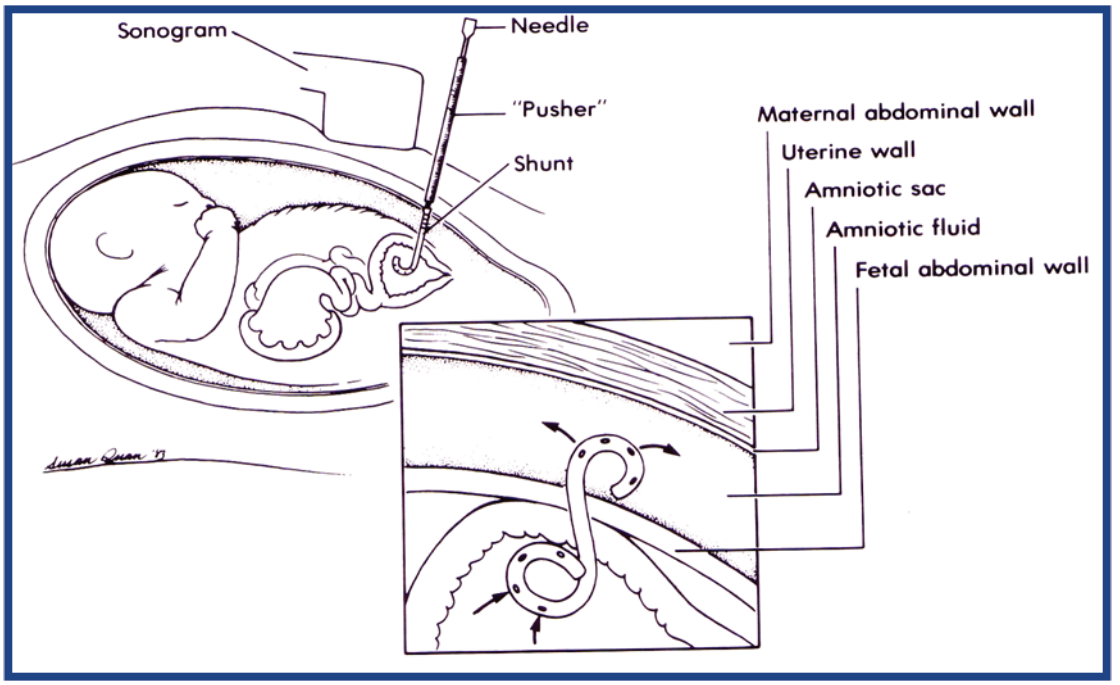
It is up to you to decide whether or not to take part. We will discuss this with you at your next appointment. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at

any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I decide to take part in the trial?**

When we see you for your next appointment, we will ask you for your consent to take part in this study. As we don't know whether this treatment really helps babies with this problem, we need to divide the pregnancies into two groups –those who have the shunt and those that don't. A computer at the central trial office will allocate you to a group in a random manner, like tossing a coin. Your specialist will not know the result in advance and cannot influence this. We will then be able to compare the group of untreated babies with the group who received treatment, to see if shunting makes a difference.

Having a vesicoamniotic shunt placed is similar to the test you underwent today when we sampled the baby's urine. The needle we use is a little bigger, so we use local anaesthetic to numb your skin. We also give you some antibiotic tablets to minimise the risk of introducing infection. We then use ultrasound to guide the needle into the baby's bladder, and use the needle to introduce a small plastic tube that will allow urine to drain directly from the bladder into the amniotic fluid around baby.




The whole procedure may take 30 minutes, but the bit with the needle usually only takes 5-10 minutes. After the procedure you may go home if you feel well enough, or stay in hospital overnight if you prefer. We will keep a frozen sample of your baby's urine for future research.

The procedure is not experimental and we have used it successfully for a number of years. However, no one in the world knows if it is the placement of the shunt that really helps in these cases. Whether or not the shunt is placed, we will arrange for monthly follow up scans. Once the baby is born it will be assessed by experienced paediatricians who will arrange further tests and treatment as required.

We aim to collect information on your baby's progress until he or she is five years old. Most of this information will be obtained from the routine tests and examinations that your paediatrician will arrange, however we may wish to send you a questionnaire at some stage to find out your views and how well your child is able to go to the toilet.

## What are the alternatives?

If you chose not to take part in the trial, we would offer you treatment according to current "best practice". At present this would not usually involve placing a shunt. In very rare circumstances the specialist may consider the shunt is the only possible treatment. If you do not want to participate in the trial or your specialist thinks it is best to either shunt or to continue observation, you will not be part of the PLUTO Trial, However we would like to collect information on your pregnancy for a PLUTO Registry, with your consent. The registry information will be collected until your child is 5 years of age and will be used together with the trial information.

## What are the risks?

There is a 1-5% chance that the procedure of inserting the shunt may cause you to miscarry, the baby to die or you to go into preterm labour. There is also a 2% risk of the membranes rupturing before labour. As with any procedure there is a small risk of infection and of adverse reaction to any drugs used e.g. anaesthetic, antibiotics. Occasionally the shunt fails (either due to blockage or the shunt moving out of the correct position), in which case we would discuss placing a second shunt with you. It is possible that placing the shunt could injure your baby and worsen its chances of survival. Rarely inserting the shunt can cause injury to the mother e.g. to blood vessels, bowel.

## What are the benefits?

Placing a vesicoamniotic shunt may increase the chances of survival for your baby and improve the long-term function of its kidneys and bladder. With your help, we will be able to answer this question.

## What if new information becomes available?

If new information on the treatment of fetal bladder outflow obstruction from other research becomes available during the course of this study, we will tell you about it. If as a result you wish to withdraw from the study, we will make appropriate arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.

Also, after running more tests we might consider it to be in your best interests to change the treatment. We will explain the reasons for this and arrange for your care to continue. The information we collect from babies with this condition is extremely important, so even if a change of treatment is necessary we would appreciate your consent to continue collecting information.

## What if something goes wrong?

You will remain under our care for the duration of this pregnancy. We will see you on a regular basis and address any problems as they arise.

If taking part in this study harms you or your baby, there are no special compensation arrangements. 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 should be available to you.

## What happens if I change my mind during the research study?

You can change your mind at any time; although once a vesico-amniotic shunt is placed it cannot be removed until the baby is born. However, it is important for the reliability of the trial that we collect as much information as possible on all babies, so it would be good if you allowed us to continue using the routine data for the trial.

## Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Your doctor will send information about your baby's progress to the central trial organisers. This will be put on to a computer and analysed but held in strict confidence. No named information will be published in the trial report. Information held by the NHS and records maintained by the Office of National Statistics may be used to keep in touch with participants and follow-up the status of the baby. Occasionally, inspections of clinical trial data are undertaken, for example to ensure that all participants have given consent to take part. But apart from this, only the study organisers will have access to the information kept centrally.

## What will happen to the results of the research study?

Once the trial is finished we will publish the results in a medical journal so that others can benefit. We will also publicise the results on the trial's web site www.pluto.bham.ac.uk and send a newsletter to all participants. The first results will be available about six months after the trial stops recruiting babies.

## Who is organising and funding the research?

This study is being organised by doctors and researchers at the Birmingham Women's Hospital and University of Birmingham, in collaboration with other doctors at fetal medicine centres across the world. The study is funded by the Wellbeing of Women charity and Health Technology Assessment Programme. No one receives any money for you taking part in this study.

The PLUTO trial has been reviewed and approved by the Nottingham Research Ethics Committee and local research ethics committees.

## What if I have more questions or do not understand something?

Having read this leaflet, it is hoped that you will chose to take part in the PLUTO trial. If you have any questions, you can ask us at any stage, either while you are here or by telephone.