Participant Information Sheet

Would you be willing to join us in a research project?

A new urinary catheter designed to improve bladder drainage: first-in-human testing of the Flume catheter

Stage 1a - patients undergoing general anaesthetic cystoscopy

Invitation to participate in a study

North Bristol Trust are Sponsoring a study to test the performance of a new type of indwelling catheter called the Flume catheter. An indwelling catheter is a flexible tube which is inserted into the bladder and left in place to drain urine. This study will test the safety of the Flume catheter and will look at how it can be inserted and removed. Although the Flume catheter has already been extensively tested in the laboratory, this will be the first time that the Flume device has been used in people.

We would like to invite you to join us in a research study. Before you decide whether to take part, we would like you to understand why the study is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your General Practitioner if you wish. Someone from the study research team will go through this information sheet with you. Please ask if there is anything that is not clear to you, or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of this study?

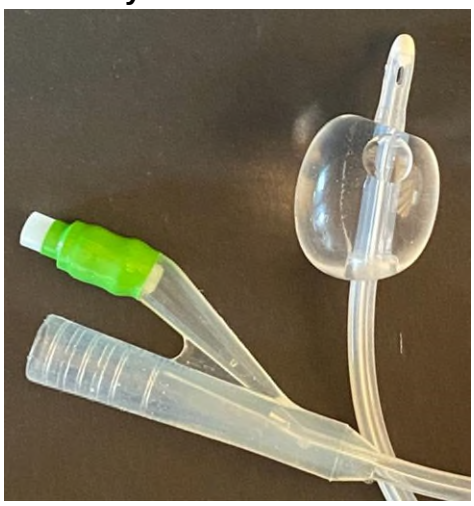
The study you are being invited to take part in is a research study to test the performance of a new type of catheter called the Flume catheter (more information is provided about the Flume catheter below). We wish to confirm whether the Flume catheter can be easily and safely inserted and removed after use. The aim of the study is to determine both safety and ease of use of the Flume catheter. We need to know what nurses and doctors think about the Flume catheter, before a randomised controlled trial of the Flume catheter versus the current Foley standard of care is designed and conducted. We would also like to get your opinion on the level of comfort you feel after it has been inserted and removed via the urethra (the urethra is a tube connected to the bladder that allows urine to pass from the bladder and out of the body). Your involvement would be very much appreciated because it is really important that we understand the patient perspective prior to further study. You would be helping us plan the research and also guide us about what we should be looking for when trying to decide how good the device is.

What is the Flume catheter?

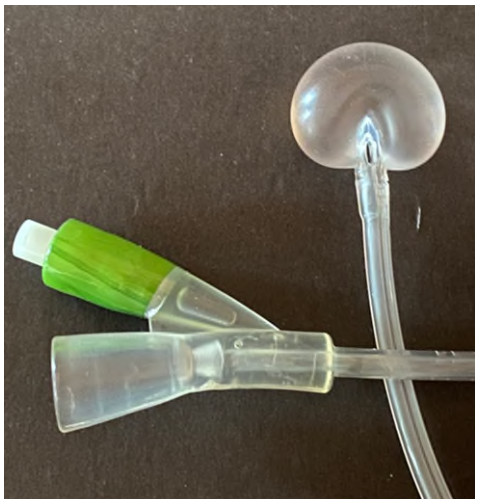
A catheter is a flexible tube which drains urine from the bladder. The catheter is inserted through the urethra into the bladder. Once the catheter is in place a small balloon at the catheter tip (inside the bladder) is inflated to prevent the catheter from falling out. Urine drains from the bladder into a catheter bag.

The Flume catheter is very similar to a well-known catheter called the Foley catheter (see pictures below) which has been safely used in millions of patients. The Flume catheter is designed to reduce infection, blockage, leakage, discomfort and pain, which may occur in long term catheter users. One of the aims of the study is to confirm the reduction of these side effects. The device provided is sterile and is for single patient use.

The Foley Catheter



The Flume Catheter



It is hoped that this study will be able to determine whether the Flume Catheter will reduce the amount of pain, infections and/or blockages than the traditionally used Foley catheter.

The body always tries to get rid of unnatural things. The bladder will contract painfully at times to try to get rid of a catheter. The Flume catheter is smooth and round without a tip. It also has half the length in the bladder than the Foley which should mean less pain.

Additionally, the tip of the Foley catheter may damage the lining of the bladder which can lead to infections and blockage of the catheter. The lining is damaged both by constant rubbing but also by tearing off mucosa (cells that line the bladder) that gets sucked into the drainage holes. In the Flume catheter the tip of the device is protected by the balloon so bruising to the nearby tissue should be eliminated. The design of the Flume catheter also allows the urine to drain out of the bladder completely.

The Flume catheter does not yet have a CE mark. A CE mark is a quality assurance mark like a 'Kite-Mark'. It is the intention to apply for a CE mark following the successful completion of the study.

If you would like to learn more about the Flume catheter please ask a member of the research team.

Why have I been asked to take part in this study?

We are looking for patients attending the clinic for routine cystoscopy and who are willing to help us with this research project. We are asking you to take part in this study because during your cystoscopy you will be under general anaesthetic and we do not expect that you will experience any discomfort during the insertion and removal procedure which will be carried out by the investigating Urologist.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part, you are free to withdraw from the study 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 quality of care you receive. If you withdraw, unless you object, we will still keep records relating to the treatment given to you, as this is valuable to the study. If you decide that you would like to withdraw from the study please contact the research team using the contact details provided below:

[To be localised at site level]
Name:
Contact Details:

How long will the study last?

The catheter will be inserted and removed while you are under general anaesthetic. The cystoscopy is likely to take 15-20 minutes with an additional 10 minutes for catheter placement. After seven days a Research Nurse will contact you by telephone, or webconference if you prefer, to check if you experienced any discomfort after taking part in the study. This should take no longer than ten minutes.

What happens in this clinical study?

If you decide to participate in this study you will meet with your doctor or nurse and be asked to sign a consent form to confirm that you are willing to take part in the study. Taking part in the study requires you to have the Flume catheter inserted into the urethra. After the Flume catheter has been inserted, the investigating Urologist will check its position and function by both observing urine flow and performing gentle inflation to ensure the balloon is in the bladder. After inflation, mild traction is applied to the catheter and resistance confirms the balloon is correctly inflated. Subsequently the Urologist will remove the catheter. The catheter will be kept until after your follow up interview with the research nurse. This is a precautionary step in case of any safety concerns. The catheters will be disposed of after your interview.

The study will involve the following:

1. As you are having a diagnostic urological cystoscopy you have been sent information about the study. Prior to deciding whether to participate in the study you will be given the opportunity to ask questions about what the study will involve.
2. If you agree to participate in the study, you will be asked to sign a consent form.
3. On the day of your cystoscopy, and while under general anaesthetic, the Flume catheter will be inserted into your urethra by a Urologist.
4. The Urologist will inflate the balloon on the catheter and verify the position of the device.
5. After checking the position of the Flume catheter, the Urologist will remove the Flume catheter while you are still under general anaesthetic. The Bristol Urological Institute will store the catheter for a week, but no analysis will be performed on the catheter.

6. You will be free to go home soon after the cystoscopy. You will be given a form to complete at home to record if you have had any bladder related problems since your cystoscopy.
7. About one week after your cystoscopy (and removal of the Flume catheter) you will be asked a few questions about whether you feel discomfort after having taken part in the study. The questions will take place either via the telephone or webconference and should take less than ten minutes. The information you give will be entered into a database for analysis. Once you have answered the questions, we will dispose of the catheter.

Please ask if you would like more information about this.

Potential Risks and Benefits?

With any medical treatment or procedure, there is the risk of complications, from the medication, from the anaesthesia and from the procedure, such as infection. Based on the millions of patients who use a urinary catheter the chance of any complications occurring during or after the procedure is very small. The main disadvantage of using a urinary catheter is that it can sometimes allow bacteria to enter the body. This can cause an infection in the urethra, bladder, or less commonly the kidneys. These types of infection are known as urinary tract infections (UTIs) and should settle quickly with a course of antibiotics. As the Flume catheter will be in place for less than 20 minutes the chances of infection are very unlikely.

Other, less common, potential problems include:

- injury to the urethra (the tube that carries urine out of the body) when the catheter is inserted
- injury to the bladder or rectum (back passage) caused by incorrectly inserting the catheter

Occasionally, catheter balloons do not deflate for removal; for Foley catheters, this requires urological intervention, using a needle to perforate the balloon. The Flume design makes it possible to insert a wire along the drainage tube to burst the balloon.

There will be no direct benefit to you if you take part in this study. We believe that the new device is safe but we need to demonstrate whether it is better than the traditional Foley catheter.

We sincerely hope you will agree to participate in the trial and give us valuable user experience which will guide future development. The Flume catheter could be a step-change for catheter users and you could play a part in improving their quality of life in the future.

Who has reviewed the Flume study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This research study has been reviewed by the ??? Research Ethics Committee who have agreed to the study (Ref XXX).

Will my taking part be confidential - how will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name, initials, gender, date of birth and address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information

• at www.hra.nhs.uk/information-about-patients/
• by our leaflet available from www.nbt.nhs.uk/PatientResearchdata
• by asking one of the research team
• by contacting Helen Williamson (Head of Information Governance) at helen.e.williamson@nbt.nhs.uk or by ringing 0117 41 44767.

Contact for further information

If for any reason you are experiencing some difficulties during your involvement in the study and require further support from the research team, you can either contact them directly (contact details below) or you can request to be called by a member of the research team.

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the study. If you require any further information or have any concerns while taking part in this study please contact:

XXXXXXXXXXX

Emergency contact number
If you need to contact a doctor or nurse in an emergency please use the following number:
XXXXXXXXXXX

What should I do if there are any problems or I would like to make an independent complaint?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the North Bristol NHS Trust but you may have to pay your legal costs. NHS-sponsored research studies such as this one are covered by NHS indemnity (the same indemnity that applies to any patient in the NHS). In the unlikely event that you feel that you have been adversely affected by participating in this study, you should contact the research team as soon as possible. The team will arrange to meet you as soon as possible to discuss your concerns. Should you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms will be available to you. Please visit www.nbt.nhs.uk/patients-carers/feedback for further information about how to make a complaint or contact the North Bristol Trust Hospital Patient Advice and Liaison Service (PALS) on **0117 414 4569**. PALS can also provide confidential advice and support to patients, families and their carers.

You can leave this study at any moment and for whatever reason. Furthermore, this will have no detrimental effect on your subsequent treatment. Treatment will carry on as if you had never been part of the study.

If you need any further information your Urologist can be contacted at:
XXXXXX

Urologists name: (*To be inserted)*

Urologists telephone number: (*To be inserted)*

What do I do now?

If you are interested in taking part in the study, please let a member of the study team know, in person, when you next come to the hospital, or by contacting the study team at XXXX.

Thank you for considering taking part in our research.

If you have received this information in the post and you would like more information or are willing to participate in the study please detach and return this slip in the pre-paid envelope to:

Research Nurse
Bristol Urological Institute,
Learning and Research
Southmead Hospital
BS10 5NB

I am interested in taking part in the study to test the Flume catheter and am willing to be contacted. I understand that I am under no obligation to participate.

Name: _____

Address: _____

_____

_____

_____

Post Code: _____

Tel: _____

Email: _____

Most suitable time for contact: _____

9