**INFORMATION SHEET AND CONSENT BY SUBJECT FOR PARTICIPATION IN RESEARCH STUDY**

**A prospective single centre randomised control trial of magnetic ureteric**

**stents versus conventional ureteric stents.**

**Name of Chief investigator: Mr Derek Hennessey**

**The contact number of the chief investigator: 021 493 5227**

You are invited to take part in this research study. Before you decide, it is essential for you to understand why the research is being carried out and what is involved.

Please take time to read the following information carefully and discuss it with others if you wish. The researchers will discuss this study with you and answer any questions you may have.

When you are happy that you understand what is involved in this study, you will be asked to sign a consent form if you wish to participate.

**Nature of the study:**

At end of your procedure, your surgeon may decide that you need to have a temporary JJ stent placed in your ureter (the tube connecting the kidney to the bladder).

Currently we use two types of stents. These stents are commonly used worldwide, however there is not enough evidence at present to chose one type of stent over another.

The purpose of this study is identify if one type of stent is superior to another in relation to patient comfort (reducing stent related symptoms) and overall experience including the removal of the stent.

**If I take part in this study, what will I have to do?**

If you agree to take part in this study, one of the researchers will use a random number generator to choose one particular type of stent for you.

When you come back for your stent removal, we will ask you to complete a questionnaire related any stent symptoms you may have experienced. Then we will ask you to rate any discomfort you experience during your stent removal.

All of your information is completely confidential and your name or details will not appear in this study.

**Potential risks and benefits**

There is no direct benefit to you from taking part in this study. However, there is a benefit to society, as participating in this study will increase our knowledge about which type of stent is more comfortable for our patients and which removal method is least painful.

Your treatment may require a stent regardless of being in the study. Both types of stents are commonly used already and participating in this study has no risk to your health.

**Do you have to take part?**

It is up to you to decide whether or not to take part. Participation in this study is voluntary. If you decide to take part, you are still free to withdraw at any time during the study 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 clinical care you receive.

**What will happen to the information which you give?**

The information that has been gathered from you will be stored on a secure server at Mercy University Hospital. Your name is not on the questionnaire, just your study number so that it is anonymous.

The information you have given will not be shared with anybody who is not on the research team. When the members of the research team look at the information gathered from the study, they will not know which information was gathered from you, and which was from the other people who took part in the study.

On completion of the project, the information will be destroyed, a copy of your signed consent form will be kept on your medical file.

**Any further queries?**

If you need any further information, you can contact the chief investigator; Mr Derek Hennessey, 0214935227.

**Agreement to consent**

* The research project and the procedures associated with it have been fully explained to me.
* I have had the opportunity to ask questions concerning all aspects of project.
* I am aware that participation is voluntary and that I may withdraw my consent at any time.
* I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me.
* Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner.
* When required by law, the records of this research may be viewed by government agencies.
* I understand that the investigators have such insurance as is required by law in the event of injury resulting from this research.
* I, the undersigned, hereby consent to participate as a subject in the above described project.
* I have received a copy of this consent form for my records.
* I understand that if I have questions concerning this research, I can contact the chief investigator listed above.
* I understand that the study has been approved by the Cork Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact CREC at Lancaster Hall, 6 Little Hanover Street, Cork, 021 4901901 or email [crec@ucc.ie](mailto:crec@ucc.ie).

**Please tick the following**

|  |  |  |
| --- | --- | --- |
| I have read and understand the study | Yes | No |
| I agree to participate in this research study | Yes | No |
| I grant permission for the data collected to be used in this research only | Yes | No |

Researcher Signature

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Signature of study participant

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Date

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