**The SAFE study - Sexual Assessment after Focal therapy with various Energy sources: a mixed methods study (prospective cohort)**

**Participant information sheet**

We would like to invite you to take part in a research study. The study is evaluating the experiences of patients treated by focal therapy for localised prostate cancer. Before you make any decision regarding participation, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. If you have any further questions, please contact the Project Manager (contact details provided at the end of this leaflet).

**What is the purpose of the study?**

The purpose of the study is to better understand the evolution of men’s sexual function after focal treatment for localised prostate cancer. Besides the use of questionnaires, we would like to go into deeper details to gain in-depth knowledge of what is happening in the weeks and months following surgery. Two telephone interviews will be taking place before treatment and 3 months after the surgery to better understand your experience, and symptoms.

**Who is conducting the study?**

This study has been organised by University College London and funded by the Fondation de France, the European Urology Scholarship Program and Angiodynamics. It is being undertaken independently by a research team, led by a postdoctoral researcher from University College London. The study team also involves a qualitative researcher and an andrologist.

**Why have I been selected?**

You have been selected because you are awaiting treatment by focal HIFU, focal cryotherapy or focal irreversible electroporation and are currently sexually-active. We would like to know what your preoperative status is, what your expectations regarding treatment effects are, and what the evolution of your sexual function at 3 months after treatment is.

**Do I have to take part?**

No. A decision to take part in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. Any decision regarding participation will be confidential between you and the research team. You are also free to withdraw from the study at any time. Your future care will not be affected.

**What does agreeing to take part involve?**

Your involvement would be to take part in two telephone interviews with a member of the research team. A first interview will be scheduled once your treatment is planned and before surgery. We will discuss your preoperative sexual status and record your expectations. You will also be asked to fill-in online validated questionnaires. The interview will take place at a convenient time for you. A second interview will be planned at 3 months, at the time of your follow-up clinic visit. The main topic of discussion will be the evolution of your sexual function after the treatment. Questions will be asked regarding various components of your sexual function such as erection, ejaculation, orgasm, changes in the size or shape of your penis, etc. We will ask you to fill-in another set of questionnaires. Each interview will last for around an hour and will be audio recorded. If you agree to it, we may contact you again to gather further information after the interview. Once anonymised, recordings will be sent to external secretarial services (HW secretarial services, Bristol, UK) for transcription. The recordings will be used for training of the research team, quality control, audit and specific research purposes. Anonymised data collected from the interview will be analysed independently by the research team. Your enrolment in the study will last for around 3 months, and you will remain free to withdraw at any time.

**How will we use information about you?**

In this research study we will use information from you and your medical records. We will only use information that we need for the research study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it.

We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

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

This information will include your *full name,* *patient number,* age, employment status, ethnicity, treatment type and date, sexual orientation and detailed sexual function. 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.

Your data will not be made available to any commercial organisations but remain solely the responsibility of the researcher(s) undertaking this study

**What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, and we will delete your data unless agreed otherwise

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

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to g.fiard@ucl.ac.uk

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at **data-protection@ucl.ac.uk**

This ‘local’ privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our ‘general’ privacy notice:

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the ‘local’ and ‘general’ privacy notices.

The lawful basis that will be used to process your personal data are: ‘Public task’ for personal data and’ Research purposes’ for special category data.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise (no one can identify you based on the data) or pseudonymize (a code is used to identify your data, known only to the research team) the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at **data-protection@ucl.ac.uk****.**

**What are the risks of participating?**

We believe that the risks are minimal. We will try to accommodate your schedule to minimise the inconvenience in taking part in the interview. You may also worry about experiencing some discomfort discussing intimate matters with a researcher. The study team will make sure that the training of the interviewer and interview methods used will allow you to feel at ease during the interview. You will be free at any stage to withdraw from the interview or take time out if you wish. We will offer participants the possibility to receive the transcript obtained from the interview. If we were to discover unexpected findings related to your health during the interview, we would contact your GP for future action.

**How will I benefit from this study?**

We hope you will find the experience of taking part in the interviews interesting and useful. You will have the opportunity to receive feedback from the study team in a short report of the overall interview findings if you wish to. You will be given a £40 gift voucher in compensation for your time.

**What will happen as a result of the study?**

The data collected from you will be aggregated with the data from other participants in the interviews, and this will be analysed and used to produce a report which will be made available for all participants. The results obtained will be presented during national and international conferences, and submitted for publication in international peer-reviewed journals. We expect that the depth of the details obtained will help future patients by providing them with more accurate and detailed information before their treatment and during their follow-up.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Research Ethics Committee. The study has also been scientifically reviewed by independent peer reviewers prior to funding being given.

**What should I do now?**

You should take enough time as you feel you need to consider whether to take part. If you do wish to take part, there is a contact email/number of the Project Manager to reply to below. The research team will then contact you to arrange a time for the interview and forward a consent form for you to sign. All consenting processes for this study will be conducted remotely (electronic consenting). Before you sign the electronic consent form, you will be given the option to discuss the study with a member of the study team. If you do not wish to take part, then you are not required to do anything, and we will not contact you again.

**What will happen if I don’t want to carry on with the study?**

If after consenting to take part in the interview you subsequently change your mind about participating, you can withdraw from the study at any time (including during or after the interview itself). Any data collected from you would not be included in the study.

**What if something goes wrong?**

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor’s (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Gaelle Fiard who is the Chief Investigator for the research and is based at Charles Bell House. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital’s Patient Advisory Liaison Service (PALS).

Site: University College London Hospitals NHS Foundation Trust

Address: Ground Floor Atrium, University College Hospital, 235 Euston Road, London NW1 2BU

Tel: 020 3447 3042

Email: uclh.pals@nhs.net

When contacting them, please quote the study number at the footer of this information sheet.

**Further contact**

If you have any further questions, then please feel free to contact Gaelle Fiard, Project Manager.

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Thank you for your time