**Patient information sheet**

 **PART 1**

**Protocol number: 16/0590**

**Study Title:** A Randomised Clinical Trial Of Manual versus iSYS1 trajectory guidance system assisted Stereoelectroencephalography Electrode Placement

**Invitation**

We would like to invite you to participate in a randomised control trial ( where you are randomly allocated to which procedure you will undergo), comparing the timing and accuracy of Stereoelectroencephalography (SEEG) electrode placement between the currently used ‘manual’ technique and electrode placement using the ‘iSYS trajectory guidance system assisted’ technique. 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.

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

Stereoelectroencephalography (SEEG) is an investigation used to guide definitive epilepsy surgery by enabling the identification of the part of the brain that is giving rise to seizures. The procedure involves the placement of depth electrodes within the brain to measure the electrical activity during seizures. This carries the risk damaging blood vessels in the brain, which can lead to bleeding, as well damage to important neurological structures. The safety of the procedure is dependent on the accuracy of electrode placement. We would like to compare the surgical time, accuracy and complication rates between 1) the currently used manual and 2) using the iSYS1 trajectory guidance system for SEEG placement. The iSYS1 trajectory guidance system is a small robotic device that has been developed to allow alignment to the planned trajectory with high levels of accuracy. The iSYS1 trajectory guidance system is under the control of the surgeon at all times and does not insert the electrode.

**Why have I been invited?**

You have been chosen to be invited because you are due to be admitted to the National Hospital for Neurology and Neurosurgery, for SEEG placement as part of the investigations being carried out for the consideration of epilepsy surgery. 32 participants will potentially be recruited into this study.

**Do I have to take part?**

It is entirely up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form, of which you will keep a copy. You will still be free to change your mind at any time, and without giving a reason. This would not affect the standard of care you receive. With your agreement we will inform your GP of your participation in this project.

**What is involved in the study?**

If you agree to take part in the study you will be randomised to having the SEEG electrodes placed with either the currently used ‘manual’ or ‘the iSYS trajectory guidance system” technique. Randomisation (randomly allocated to one of the 2 techniques) will occur prior to the surgery and you will not be informed as to which technique will be undertaken.

Regardless of which technique you receive it is routine for you to be admitted the day before surgery for pre-surgical anaesthetic and surgical assessment. On the morning of surgery, markers are placed in the skull under local anaesthesia and a CT scan of the head is performed. You will then undergo a general anaesthetic prior to the SEEG electrode placement using one of the two techniques:

* + 1. The manual technique of SEEG placement involves the use of a neuronavigation system and the surgeon aligning a mechanical arm along a pre-planned trajectory. Once the trajectory has been aligned a skin incision is performed and a small hole is drilled through the skull. A metal bolt is then screwed into the skull through which the electrode is inserted along a premeasured length to reach the target in the brain. The electrode is then secured in place by the bolt.
		2. The iSYS1 trajectory guidance system technique of SEEG placement involves the use of a neuronavigation system relaying the plan information to a small guidance system that the surgeon places a few centimetres from the surface of the scalp and the guidance system, through a series of small steps will then align to the pre-planned trajectory with a high level of accuracy. Once the trajectory has been aligned a skin incision is then performed and a small hole is drilled through the skull. A metal bolt is then screwed into the skull through which the electrode is inserted along a premeasured length to reach the target in the brain. The electrode is then secured in place by the bolt.

The main difference between the two SEEG insertion techniques is that the alignment of the drill guide to the pre-planned trajectory on the neuro-navigation system is either performed manually by the surgeon or by the guidance system. The accuracy of both of these techniques is monitored throughout by the neuronavigation system.

As is current standard practice, we will carefully follow you up after surgery and you will undergo a CT scan of the head that day to detect any potential complications from the implantation and to determine the electrode positions. We will then carry out an MRI scan to give more precise information of the location of the electrodes. You will then be taken to the video-EEG telemetry unit where recordings from the electrodes will be undertaken. The duration of the recording is dependent on the number and types of seizures you have. On average recordings are performed for up to 7-10 days but you may require longer if this is need to confirm the seizure onset zone.

**What will happen to me if I take part?**

You will be contacted or met by one of the research team, who will explain the study again. You will have at least 24 hours to consider whether you wish to participate. We will ask you to sign the consent form of which you will be given a copy. You will also have the opportunity to contact us and ask questions at any point. The rest of the preparation for surgery, the surgery and the follow-up afterwards will continue in the standard way. The only difference will be the technique used for alignment of the drill guide.

Sometimes we don‘t know which way of treating patients is best. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

Your participation in this study is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are free to decline to enter or to withdraw from the study at any time without having to give a reason; if you choose not to enter the study or to withdraw once entered, this will in no way affect your future medical care and the SEEG implantation will go ahead using the ‘manual’ technique as this is our current routine for performing this procedure.

**Have Guidance systems** **been used before for SEEG?**

Guidance systems from a variety of manufacturers are being used throughout the world for SEEG implantations. Based on published data from these centres there is no additional risk from guidance system -assisted implantations and it has been suggested that guidance system-assisted implantations are quicker and more accurate than manual implantations. This particular guidance system has recently been used in epilepsy patients in Vienna, Austria. They have found the iSYS1 trajectory guidance system is safe and provides accurate electrode placement.

**What are the potential benefits?**

The neurosurgical services in our hospital have a very high level of quality and safety. Any surgery carries some risks, even when performed at the highest safety level. It is one of the goals of our project that individual neurosurgical operations will be planned and carried out more precisely, resulting in fewer complications. We have put in place all measures to reduce the risks of neurosurgery, with either method of SEEG electrode placement. These measures have been approved by two comprehensive reviews, including review by National Hospital for Neurology and Neurosurgery and the Institute of Neurology National Research Ethics Service (NRES) Committee London-Queen Square

**What are the potential risks?**

All neurosurgical interventions carry risk. In particular, the risk of bleeding, infection and neurological injury due to misplacement of the SEEG electrode are specific risks associated with this procedure. The study is aimed at comparing the time and accuracy of SEEG electrode insertion. Previous studies have shown that the use of the iSYS1 trajectory guidance system does not result in an increase in such risks.

**What expenses are covered?**

There are no extra reimbursements available for inclusion within this study outside of those that you may be eligible to as part of your routine care.

**What happens when the research study stops?**

After completion of the trial the results will be presented at scientific meetings and submitted for publication in a leading medical journal. Should you wish to find out which intervention arm you underwent please contact us and we will be able to provide you with this information after completion of the trial.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

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

Information about you will be stored on secure NHS and University computers during this research project. This will include your name and contact details to allow us to keep in contact with people who have taken part in the study. All information will be kept secure and strictly confidential, accessible only to those involved directly in this research.

No information will be passed to any third parties or outside the EU for any reason without your explicit consent. The information will be kept securely at the National Hospital for Neurology and Neurosurgery in a locked cabinet and in a secured, password-protected computer under the supervision of Prof John Duncan. Your data will be stored for fifteen years following the project completion. It will be pseudo-anonymised, which means that your name will not be with the research data but linked by a separate code. All data will be stored under password protection. Your personal information will be kept separately from the data to exclude a chance of identification.

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

This completes part 1.

*If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.*

PART 2 of the Patient Information Sheet

**What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study he may ask you to sign an agreement outlining the discussion.

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

*If you withdraw from the study, we will destroy all your identifiable data. Data collected up to your withdrawal will not be used as part of this study.*

**What if there is a problem? What happens if something goes wrong?**

If you are not happy with any aspects of the study, you have the right to complain through the UCLH complaints procedure: UCLH NHS Foundation Trust Patient Advice and Liaison Service (PALS) located at the National Hospital for Neurology and Neurosurgery, London WC1N 3BG **020 3448 3237**.

Taking part in this study will in no way affect your legal rights. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, you may have grounds for legal action, but you may have to pay for this. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanisms should be available to you.

**Will my GP be informed of my involvement?**

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study.

**What will happen to any sample I give?**

All bloods samples will be processed in the same way as routine blood samples from the Hospital. We do not intend to use these samples for future research.

**Will any genetic tests be done?**

This study does not use any form of genetic test.

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

The results of this research may be published in scientific literature. However, this will never include any identifying details and your identity will always remain anonymous. Details of publications by the Department of Clinical and Experimental Epilepsy, UCL Institute of Neurology, Epilepsy Society and UCL Hospitals NHS Foundation Trust can be obtained from our website. If you are interested to read the publications arising from this research we will send you copies.

With your consent, healthcare professionals involved in your care, including your GP or any hospital specialist, will be informed of both your participation in the study and any outcome resulting from your involvement, if the results are considered to be relevant to your on-going care.

**Who is organising and funding the research?**

This study is organised by the Department of Clinical and Experimental Epilepsy of the Institute of Neurology, University College London and the National Hospital for Neurology and Neurosurgery. This study has been reviewed and funded by the Wellcome Trust.

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**Who has reviewed the study?**

All proposals for research involving human subjects are reviewed by an independent group of people , called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by, National Hospital for Neurology and Neurosurgery and the Institute of Neurology National Research Ethics Service (NRES) Committee London - Queen Square.

**Feedback**

If you participate in this research project, we would like your feedback afterwards. Although this investigation was thoroughly planned and is based on previous experiences, we anticipate that you might find that parts of it could be improved. Please give us feedback of what we should change and what could be made better. Please also indicate whether you would be willing to be invited by phone, e-mail, mail or personal contact to participate in a research project again. Thank you.

**Further Information**

If you, your relatives or friends have any questions about participating in this study, please contact

Prof John Duncan (tel: 020 3448 8612; fax: 020 3448 8615; email: j.duncan@ucl.ac.uk) or Mr Andrew McEvoy (tel: 020 7380 9579; fax: 020 7380 9937; Email: a.mcevoy@ucl.ac.uk).