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PARTICIPANT INFORMATION SHEET (Cohort Study)

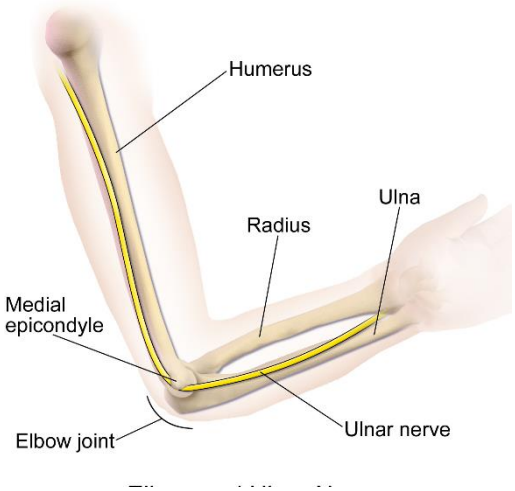
UNDER Study: Ulnar Nerve Decompression Endoscopic Randomisation Study.

The UNDER Study is comparing tow operations that can be used to treat and manage cubital tunnel syndrome (CuTS).

You are being invited to take part in the UNDER Study. Before you decide if you want to take part, it is important for you to know why this research is being done and what it would involve for you. Please take some time to read about the study below and discuss it with others if you wish. Please ask your local study team there is anything that is not clear.

What is the purpose of the study?

Cubital Tunnel syndrome (also known as CuTS, and Ulnar Nerve Compression) is a common type of nerve problem in the arm resulting in pins and needles, pain and /or weakness in the hand. It happens when the ulnar nerve, one of the three main nerves in your arm become squashed (compressed) or irritated. The condition affects approximately 6% of the population. For those whose symptoms are not managed, doctors can offer surgery. This surgery is called ulnar nerve decompression surgery.



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There are currently two ways of performing ulnar nerve decompression in the UK, they are called **open** decompression surgery and **endoscopic** decompression surgery.

Open decompression surgery has been around the longest in the UK. It is where the nerve is accessed by a cut in your skin which is generally about 5 cm long and runs alongside the nerve.

With endoscopic decompression surgery there is a shorter 2-3 cm long cut into the skin and then a camera and light is used to see the nerve rather than cut all the skin overlying the nerve. There is some evidence that by having a smaller cut (incision) might reduce the complications that are attributed to longer incisions. However, sometimes surgeons may need to change to open decompression if there are problems in seeing the nerve or other complications.

Both surgical techniques have potential advantages and disadvantages and the UNDER study is investigating which is better both in the short and longer term for patients with CuTS, and the results of this study will provide evidence to guide future decision making for patients and clinicians in the treatment of CuTS.

This study will consist of two phases. The first to assess the training of experienced decompression surgeons in the endoscopic technique and how well patients recover post-surgery as, although both techniques are performed within the NHS and the surgeon has been trained in performing both techniques, endoscopic decompression is less widely used. The second phase will be a randomised control trial where the two techniques will be compared.

Who is taking part and why have I been invited to take part?

We hope to enrol up to 175 participants for Phase 1 of this study, aged 18-80 who have CuTS that requires surgery. We will recruit from at least 25 NHS hospitals from across the UK.

You are being invited to take part because you have been listed for surgery to treat you cubital tunnel syndrome and surgeons in your hospital are participating in the UNDER Study.

Do I have to take part?

No, taking part in research is always a choice. If you decide that you do not wish to take part, your choice will not affect the care or treatment that you receive. You are free to withdraw from the study at any point without giving a reason, and this will not affect your treatment.

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

You will be invited to complete a consent form, an assessment of your condition will be completed by the clinical team, you will be given a questionnaire to complete, and your clinical team will ensure that you are eligible for the study.

Which operation will I receive?

This hospital is currently engaged in the first phase of the study and so you will be allocated endoscopic ulnar nerve decompression.

What will happen after my operation?

You will receive standard care post-surgery whether you are in the UNDER Study or not. If you require additional treatment post-surgery, this will be directed by your local clinical team.

If you agree to take part in the UNDER Study:

You will be contacted for a short assessment of function, symptoms, and pain after 6-weeks.

At your routine 3-month appointment, the research team will assess your elbow movement, muscle power and check the scar from the surgery.

The team will also ask you to complete some questionnaires at 3 and 6 months after your surgery. Some participants will also be asked to complete a further questionnaire 2 years after surgery. These questionnaires will take around 10 minutes to complete and will ask about your health and recovery since your surgery, including any visits to healthcare professionals, such as your GP, about your elbow. You can choose to complete these online or by post. The study team may contact you to remind you to complete questionnaires, either by post, email or by phone.

What are the possible benefits and risks of taking part in the study?
We hope that the valuable information from this study will give the NHS a clear answer to the question of which surgery is the best to treat individuals with CuTS. We cannot promise that the study will help you directly, but the information we receive has the potential to benefit all those with CuTS in the future.

The procedure is already performed within the NHS and your surgeon has been fully trained to perform the operation. There is an increased risk of bruising with endoscopic decompression compared with open decompression surgery. If you have any questions or concerns about the complications associated with this injury and surgery, please speak to your local care team.

People sometimes feel uncomfortable answering certain questions about their health, or may feel unable to answer certain questions. If you feel uncomfortable at any point, then you do not have to answer the questions.

Who will know that I am taking part?

The UNDER Study research team and the healthcare professionals involved in your care. The only people who will have access to information that identifies you will be people who need to contact you about the study, or review your hospital record, or the central study team who will let your GP know if you agree to take part in the study. This may include staff from the University of Oxford running the study on a day-to-day basis, the University Hospitals Birmingham NHS Foundation Trust who are in charge of the study, the NHS Trust, and potentially a specialist group of research nurses employed by a national research support organisation called the Clinical Research Network. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. Paperwork that is completed by the research team, or the treating clinical team, will be uploaded onto an electronic database managed by the University of Oxford.

We will contact your GP (family doctor) to tell them that you have agreed to take part in the UNDER study. However, we will not share any of your study questionnaire answers with them.

Will my details be kept confidential and what happens to my data?
Yes, you will be allocated a study number and all patient information will be stored securely on the Oxford Clinical Trials Research Unit, University of Oxford computer server in accordance with data protection rules. Access to this information will be monitored and restricted to staff who require it to undertake their role. The data collected will be collected by a member of the local research team, who will enter it onto a secure system (REDCap). Personal details (e.g., name, address, email etc.) will be used to contact you throughout the study and may be used to send a summary of the results, if you would like them.

Responsible members of the University Hospital Birmingham NHS Foundation Trust, University of Oxford [and the relevant NHS Trust(s)/NHS Health Board (Scotland) name here] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?
There is no payment for taking part in UNDER Study. Clinical data will be collected at normally scheduled hospital appointments. If you receive your study questionnaire by post, a Freepost envelope will be provided so you can return the completed questionnaire to the study team.

What will happen to my data?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University Hospitals Birmingham NHS Foundation Trust is the sponsor for this study, based in the United Kingdom, and is data controller. This means that University Hospitals Birmingham NHS Foundation Trust as sponsors are responsible for looking after your information and using it properly.

We will be using information from you and your medical record in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, for which It is the University Hospitals Birmingham NHS Foundation Trust policy to store data up to 5 years after the end of the study.

UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

www.hra.nhs.uk/information-about-patients/

https://www.uhb.nhs.uk/privacy-notice

You can find out more about how we use your information by contacting understudy@ndorms.ox.ac.uk

What will happen if I don't want to carry on with the study?
Taking part in UNDER Study is voluntary; if you decide to withdraw from the study, you can do so at any time. You do not need to give a reason for your decision, and it will not affect your care in hospital.
If you were to decide to stop taking part in the study at any time, any data collected on you would be kept. You would not be contacted about the study again or have any further data collected. Any data collected up to the point of withdrawal may be used for the study.

What happens at the end of the study?
We will share the results of this study with healthcare researchers and professionals to improve the care of patients who have CuTS. Also, we will present the results in research reports and at scientific conferences, and publish them in scientific journals. The study results will also be publicly available at https://under.octru.ox.ac.uk at the end of the study. If you would like a copy of the results, please let us know this on your consent form.

We will not include any data that could identify you in the results. If any of the funders of this research ask us to make the study data available for other researchers or to themselves, we will first anonymise your information (i.e. we will take your name and other identifying details out) so that you cannot be identified.

How have patients and the public been involved in this study?

A group of patients who have had treatment for cubital tunnel have agreed to be part of the patient and public advisory group (PPAG). They have helped design the study to make it easy for patients to take part with little burden.

This advisory group will continue to support all stages of the study. We have a patient representative as part of the study team.

Further information on public involvement of clinical trials can be found through the following links:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- https://www.nhs.uk/conditions/clinical-trials/

Who is organising and funding the study?

The study is sponsored, by University Hospitals Birmingham NHS Foundation Trust. The Chief Investigator is Mr Dominic Power, a Consultant Nerve surgeon in Birmingham, UK. The Surgical Intervention Trials Unit will manage the study with Oxford Clinical Trials Research Unit at the University of Oxford. The National Institute of Health and Care Research, Health Technology Assessment programme, has funded the study (NIHR135260).

Who has approved this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by _____ Research Ethics Committee. The study reference number is IRAS: 324952

What if there is a problem?

The University Hospital Birmingham NHS Foundation Trust as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Mr Dominic Power <contact details (phone number & email)> or you may contact University Hospitals Birmingham NHS Foundation Trust on 0121 371 8006, or email r&d@uhb.nhs.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact <insert relevant NHS site phone number and email from the PALS website.

For support in Scotland, then please contact the Patient Advice & Support Service (PASS). PASS can advise those who wish to raise concerns, give feedback or comments, or make a complaint regarding the NHS care in Scotland.

PASS national helpline phone number: 0800 917 2127
PASS website (webchat): www.patientadvicescotland.org.uk

If you have any questions about the study, please contact the UNDER study team on:
Email: understudy@ndorms.ox.ac.uk Telephone: 01865 223489

Or for further information about the study, please visit the UNDER Study website:
https://under.octru.ox.ac.uk

Thank you for reading this information and *considering taking part.*

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