

UNDERSTANDING CAUDA EQUINA SYNDROME (UCES)

What is the purpose of this study?

Cauda equina syndrome occurs when the cauda equina nerve roots in the lower spine are compressed. This can cause a range of symptoms such as pain, leg weakness, leg numbness, and bladder, bowel, or sexual dysfunction. This study aims to:

- describe which symptoms people with cauda equina syndrome experience,
- look at the way that people with cauda equina syndrome are currently managed, and
- find out what happens to people after they are discharged from hospital.

This will help us plan how patients with cauda equina syndrome are investigated and managed in the future.

Why have I been invited to take part?

You have been asked to take part because you were admitted to hospital with compression of the cauda equina nerve roots.

What will happen if I take part?

One of the team caring for you will discuss the project with you and fill in the consent form for the study with you. After this, information about your symptoms, investigation and management from your medical notes will be entered anonymously into a study database by the team that are treating you. We will also send you questionnaires to complete about your symptoms. We will ask you about how you were at four time points:

1. Just prior to admission to hospital
2. On discharge from hospital
3. Six months after your operation
4. One year after your operation

We expect the questionnaires to take a maximum of 10 minutes each to complete.

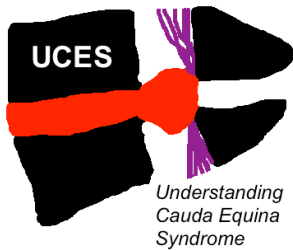
Some of the questions will be about your bladder, bowel, and sexual function. If you do not wish to answer these questions you can leave them blank. If you are happy to fill in the questionnaires electronically we will ask for your email address and you will be emailed a personalised link to fill in the questionnaires. Your email address will be stored in an encrypted study database and only the clinical team caring for you will have access to it. Your answers cannot be identified to your email address except by the team looking after you. If you would prefer to fill in the questionnaires on paper or over the telephone we will give you the first two questionnaires in hospital. We will then share your contact details with the central study team at NHS Lothian who will contact you via post or telephone to complete the last two questionnaires. We will also ask for your permission to anonymously link data collected as part of this study to any routinely collected existing records in databases or registries.

What will happen to the results of this study?

The study results will be published in journal articles and presented at conferences and at the local study centres with the aim of improving care for people with cauda equina syndrome in the future. We will also share the results of the study with all the participants using the contact details we have used to send you the questionnaires. You will not be identifiable in any published results.

What are the advantages and disadvantages of taking part?

There are no direct benefits to taking part in this study but the results from this study might help to improve the healthcare of patients in the future. This study will take up to 40 minutes of your time over the course of the year following your admission to hospital.



UNDERSTANDING CAUDA EQUINA SYNDROME (UCES)

Do I have to take part?

No, you can decide whether or not you wish to take part. Your decision will not affect the care that you receive. If you decide to take part you are still free to withdraw from the study at any time without giving a reason. If you don't want to carry on with the study after you have signed the consent form, please tell us that you want us to stop sending you the questionnaires. Our contact details are at the bottom of this sheet and on all the questionnaires that we will send to you. If you become unable to make a decision about participating in this study we will not send you any further questionnaires but we will still use the data that you have previously agreed to enter into the study.

Will my study data be kept confidential?

All the information that we collect during the study will be kept confidential. For the majority of participants only anonymous data (which cannot be used to identify you) will be shared outside the NHS organisation that is treating you. If you choose to complete the questionnaires on paper or over the telephone, or if we don't hear back from you then your contact details will be shared with the central study team at NHS Lothian via secure NHS email addresses. The central team will contact you to check if you still wish to take part in the study and how you wish to complete the questionnaires. Your anonymous data will be stored securely for five years and might be used in future ethically approved studies. The anonymous dataset may be processed on computers outside the NHS. To monitor and audit the study to ensure it is being appropriately conducted, responsible representatives from the study sponsor and NHS institutions may access your medical records and data collected during the study.

Who is organising this study?

This study has been organised by the British Neurosurgical Trainee Research Collaborative in conjunction with the British Orthopaedic Trainee Association and the British Association of Spine Surgeons. The study is sponsored by NHS Lothian. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the South East Scotland Research Ethics Committee. NHS management approval at each site at which the study is being carried out has also been given.

Who can I contact about this study?

If you have further questions about the study please discuss these with the team looking after you or your local study contact:

- Dr Ingrid Hoeritzauer, Department of Neurology, NHS Lothian, 0131 537 1000 or Ingrid.Hoeritzauer@nhslothian.scot.nhs.uk

If you would like to contact the team in charge of the study please contact:

- Miss Julie Woodfield, Department of Neurosurgery, NHS Lothian, 0131 537 1000 or julie.woodfield@nhs.net

If you would like to discuss this study with someone who is independent of the study team and is a clinician within the NHS Lothian Neurosurgery unit you can contact:

- Mr Paul Brennan, Consultant Neurosurgeon, NHS Lothian, 0131 537 2106 or paul.brennan@nhslothian.scot.nhs.uk

If you wish to make a complaint at any stage of the study, please speak to the team looking after you, your local study contact, or the team in charge of the study. If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure. Please contact:

- Patient Experience Team, 2-4 Waterloo Place, Edinburgh. EH1 3EG, 0131 536 3370 or feedback@nhslothian.scot.nhs.uk