



PARTICIPANT INFORMATION SHEET

Invitation to join the CESER study

We would like to invite you to take part in a research study called CESER – Cauda Equina Syndrome Early Recognition. This study is investigating which signs and symptoms may predict whether patients have Cauda Equina Syndrome (CES). You have been invited to take part because you are in the hospital being examined for CES. We are hoping around 2000 participants undergoing a scan for suspected CES from hospitals all over the UK will be involved in this study.

To help you decide if you would like to take part, please read the information in this leaflet. It will help you understand why the research is being done, and what it would involve for you. Feel free to discuss this information with others if you wish.

If anything is not clear about the study, or if you would like more information, please speak to your local research team or contact the CESER study team directly (contact details are at the end of this leaflet).

Scan the QR code on the right using your phone camera or follow the link below to access the study website for more information:

<https://ceser.octru.ox.ac.uk/>



What is the purpose of the study?

CES describes symptoms caused by something (usually a disc from the spine) pushing on the nerves at the bottom of the spinal cord. These nerves supply the legs, bladder, anus and sexual organs, and can become damaged if compressed for too long. Some of the symptoms include low back pain, bladder or bowel dysfunction, amongst others. Most patients with CES require an emergency operation to take pressure off the nerves.

Although lots of people attend Emergency Departments (ED) with back pain, very few of these (1-5%) have CES. To make a diagnosis of CES, a specialised scan (an MRI scan) needs to be completed. At present it is not known whether any particular pattern of symptoms can help us rule out the diagnosis without an MRI scan.

The CESER study will try to determine whether any pattern of symptoms can help us work out which patients are very unlikely to have CES. It will also help determine how future patients should be treated when they arrive at an ED with symptoms that could be caused by CES.

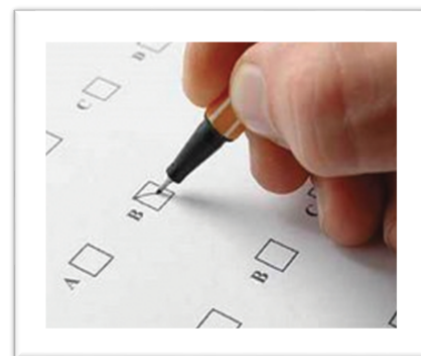
Do I have to take part?

No, it is up to you to decide whether or not you want to take part in the study. If you choose not to join the study, a researcher might ask you why, but you don't have to give a reason. Any answers you give will help make future studies better. If you do decide to take part you are free to withdraw at any time and without giving a reason. Withdrawing from the study will not affect the healthcare you receive or your legal rights.

What will happen if I decide to take part?

If you decide to take part, a researcher will ask you a few questions to confirm that you are eligible. You will then be asked to sign an electronic consent form. Your contact information will be collected so we can send you a copy of your consent form and any other relevant study documents.

After consenting to join the study, you will be asked to answer a series of short questionnaires about symptoms that can be experienced by people with CES. The questions will relate to pain, sensory changes, as well as bowel and bladder function. The completion of the questionnaires will be undertaken through a secure system on a computer or tablet. It should take about 10-15 minutes.



As part of usual standard care, you will have an MRI scan and together with your doctor, a treatment plan will be made depending on any findings.

If you are diagnosed with CES, the study team will contact you at 6 weeks and then again at 6 and 12 months after your diagnosis. We will ask you to answer some further questions about pain, bowel and bladder function. We will also ask you about your general quality of life. We will send you a web link to complete the questionnaires via email or text message. If you're unable to access an electronic device, we can contact you via telephone, or we can send out paper questionnaires for you to fill in and return to us. It should not take more than 10-15 minutes to answer the questions. If we are unable to reach you to ask you the questions using your chosen method of contact, we will try to phone you or send you the questionnaire by post. If we are unable to contact you after multiple attempts, we will check your contact details with the hospital.

If you are not diagnosed with CES, you will not be asked to complete any further questionnaires. As part of the study, we will review your hospital records after 12 months to see if you had any other diagnosis or treatments related to your back pain. This information will be very valuable for the research project. We will keep any data we have from you in line with the section below '*What will happen to my data*'.

Regardless of whether you have been diagnosed with CES or not, we may also ask you if you are willing to provide your contact details to be contacted by another researcher at a later date

about taking part in an interview to discuss your experience of being assessed for CES. Taking part in the interview is optional, and your decision to take part will not affect your inclusion in the CESER study, or your treatment.

When you are booked in to have an MRI for suspected CES, a note will be made of your age, biological sex, ethnicity, and date of injury. Your postcode will also be used, but not entered onto the system, to calculate the 'Index of Multiple Deprivation' (IMD) score, which is a widely used measure in public health research and policymaking relating to health inequalities. The data will be stored and analysed in a way that ensures that you cannot be identified from it. Collecting this information will help us to see whether the research we are carrying out is inclusive and representative of the whole UK population.

Are there any possible benefits, disadvantages or risks of taking part?

There is no direct benefit in taking part in the study. The results of the study will help us determine how patients should be diagnosed when they arrive at an ED with symptoms that could be caused by CES.

Taking part in this study will not affect any part of the care you will receive, so there will be no additional risks in taking part.

As part of the study we will ask you questions about your symptoms which some people might find upsetting. If responding to the questionnaires provokes emotional and upsetting responses, we suggest you take a break and continue at a later time.

Will my General Practitioner (GP) be informed of my participation?

As this is an observational study, and we do not interfere with your usual care we do not intend to notify your GP of your participation in this study.

Will my taking part in the study be kept confidential?

Yes. All study data will be identified only by a code. We will only use names date of birth, NHS/CHI/H&C number where this is necessary to link your NHS records/contact you etc. Information that can identify you will be held securely by the University of Oxford and your treating hospital for the purposes of the study.

In order for the trial team to be able to follow you up for the study we will use the contact details you give us. The University of Oxford and your treating hospital will use your name and health record number (e.g. NHS/CHI/H&C number) to contact you about this research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision (text messaging), survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions. We will store any research documents with your name and/or contact details

securely at the University of Oxford for 12 months after the end of the study, after which they will be deleted.

A copy of the consent form, which will contain your name, will be kept in your medical records for as long as those records are retained. Responsible members of the University of Oxford, regulatory authorities and relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

In line with what happens in the NHS, the only situation where confidentiality would need to be broken, would be if you told a health professional or research team member about something that could result in harm to yourself or others.

Any data which identifies you, such as your name, sex, date of birth, contact details, or data concerning your health is known as 'personal data'. 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 <https://compliance.web.ox.ac.uk/individual-rights>.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

Will I be reimbursed for taking part?

There is no reimbursement for taking part because all procedures are part of standard care.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you and your medical records (including your radiology report) for this research project. We will share your information related to this research project with the following types of organisations: universities, relevant NHS Trusts, regulatory authorities or companies involved in health and care research.

This information will include your:

- Initials
- NHS/CHI number
- Name
- Contact details
- Date of birth
- Biological sex
- Ethnicity

- IMD score (this is a score calculated based on your postcode).

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.

Your data from the questionnaires will also be made available to your local study team at your hospital, in this way your treating doctors will have full oversight of the data relating to your study participation.

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.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of three years, in line with the University Policy on Management of Data. Once the retention period has finished, the study data will be kept in a way that does not identify you.

We will keep all information about you safe and secure by:

- Restricting access to the research team and authorised personnel only
- Storing data on secure servers
- Storing data in accordance with all applicable regulations and ethical approvals

Your personal data will not be shared outside the UK.

You can find out more about how we use your information by contacting oxfordtrauma@ndorms.ox.ac.uk, or the CESER study team at ceser@ndorms.ox.ac.uk.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health directly from your hospital. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

In the unlikely event that you lose the capacity to make decisions about your well-being, you will be withdrawn from the study, but we will keep the information about you that we already have.

You can find out more about how we use your information by:

- asking one of the research team by sending an email to ceser@ndorms.ox.ac.uk
- calling us on 01865 xxxxxx
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: [How we use your personal data for research purposes | Compliance](#)

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: [Patient data and research leaflet-Health Research Authority](#).

What will happen to the results of this study?

At the end of the study, we will put a summary of the results on the study website and share the results with healthcare researchers and professionals to improve future patient care.

We will publish the findings of the study in medical journals and at conferences.

The funders of this research require us to make the study data available for other researchers; we will anonymise your information so that you cannot be identified.

What if there is a problem?

The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

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 Professor David Metcalfe who is the overall lead of this study on ceser@ndorms.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics & Assurance team (RGEA) at rgea.complaints@admin.ox.ac.uk.

For independent advice, the Patient Advisory Liaison Service (PALS) is a confidential NHS service in England and Wales (or Patient Advice and Support Service (PASS) in Scotland) that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS/PASS is unable to provide information about this research study. If you wish to contact the PALS/PASS team please contact **<insert relevant NHS site phone number and email from the PALS/PASS website>**.

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

Patient and public perspective has been key in the development of this research. Our patient representatives have helped us to develop the research plan. They have also reviewed this information sheet, and all other patient facing study documents. Participants' views will continue to be represented throughout the study.

If you would like to know more about getting involved in research as a patient or member of the public, please see this link: <https://www.nihr.ac.uk/patients-carers-and-the-public/> or contact: oxfordtrauma@ndorms.ox.ac.uk

Who is organising and funding the study?

The University of Oxford is sponsoring this study. It is being conducted by a research team at Oxford University led by Professor David Metcalfe, Chief Investigator and Associate Professor of Emergency Medicine. The National Institute for Health and Care Research (NIHR302219) is funding the study.

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 participants' interests. This study has been reviewed and given favourable opinion by East Midlands- Nottingham 2 Research Ethics Committee.

Participation in future research:

In the future we may wish to link the data we collect about you as part of the CESER study with other routinely collected medical data where this relates to your injury, its treatment and/or your recovery. To enable us to do so, we will ask for your specific consent to retain your NHS/CHI/H&C number, date of birth and the data we collect during the CESER study for 10 years after the end of the study. No other personally identifiable data will be retained. Ethical approval will be obtained from a Research Ethics Committee before any of your data is used for future research and we will not need to make any further contact with you. Data retained from the CESER study and any future related ethically approved project(s) will be stored securely and in accordance with all applicable regulations and ethical approvals. Agreeing to have your data stored for future research does not oblige you to take part in any future studies.

Further information and contact details:

For further information please contact:

The CESER study team:

Email: ceser@ndorms.ox.ac.uk

Telephone: 01865 xxxxxx

The Local Research Team:

Lead Research Contact: <Insert name>

Email: <Insert email>

Telephone: <Insert phone number>

If you have any questions or concerns about your clinical care, please seek care in the way that you would usually, such as 111, your GP, or Emergency Department.

Thank you for considering taking part in the CESER study