ISRCTN16828522 https://doi.org/10.1186/ISRCTN16828522

Understanding cauda equina syndrome (UCES)

Submission date	Recruitment status	[_] Prospectively registered
25/06/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2022	Nervous System Diseases	

Plain English summary of protocol

Background and study aims
Cauda equina syndrome is a potentially devastating condition caused by compression of the cauda equina nerve roots in the spine. This can result in bowel, bladder and sexual problems and lower limb weakness, numbness, and pain. Cauda equina syndrome occurs infrequently but has serious potential medical, social, and legal consequences. This study aims to identify and describe the presentation, management, and outcomes of patients with cauda equina syndrome in the United Kingdom.

Who can participate?
Patients over 18 years old with cauda equina syndrome

What does the study involve?
Patients with cauda equina syndrome are identified on admission to spinal units across the UK and asked to participate. Presenting symptoms, investigation and management are recorded and participants are asked to complete questionnaires on admission, at discharge, and at six months and one year after treatment. This provides an accurate description of the number of patients, the types of symptoms, current clinical practice, adherence to national published standards of care, and patient outcomes.

What are the possible benefits and risks of participating?
Accurate, up to date information about the presentation, management, and outcome of patients with cauda equina syndrome will inform standards of service design and delivery for this important but infrequent condition and help to identify future research priorities. 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 the participant's time over the course of the year following the initial hospital admission.

Where is the study run from?
1. NHS Lothian
2. NHS Grampian
3. NHS Greater Glasgow & Clyde
4. NHS Tayside
5. Belfast Health and Social Care Trust
6. The Walton Centre NHS Foundation Trust

7. The Newcastle Upon Tyne Hospitals NHS Foundation Trust
8. South Tees Hospitals NHS Foundation Trust
9. Lancashire Teaching Hospitals NHS Foundation Trust
10. City Hospitals Sunderland NHS Foundation Trust
11. Salford Royal NHS Foundation Trust
12. Hull and East Yorkshire Hospitals NHS Trust
13. Leeds Teaching Hospitals NHS Trust
14. Sheffield Teaching Hospitals NHS Foundation Trust
15. Nottingham University Hospitals NHS Trust
16. Derby Hospitals NHS Foundation Trust
17. University Hospital Birmingham NHS Foundation Trust
18. University Hospitals Coventry and Warwickshire NHS Trust
19. University Hospital Southampton NHS Foundation Trust
20. Cambridge University Hospitals NHS Foundation Trust
21. Norfolk and Norwich University Hospitals NHS Foundation Trust
22. East Kent Hospitals University NHS Foundation Trust
23. Oxford University Hospitals NHS Trust
24. North Bristol NHS Trust
25. Plymouth Hospitals NHS Trust
26. Royal Devon and Exeter NHS Foundation Trust
27. Taunton and Somerset NHS Foundation Trust
28. Buckinghamshire Healthcare NHS Trust
29. Milton Keynes Hospital NHS Trust
30. Barts Health NHS Trust
31. Barking Havering and Redbridge University Hospitals NHS Trust
32. King's College Hospital NHS Foundation Trust
33. Brighton and Sussex University Hospitals NHS Trust
34. St George's Healthcare NHS Foundation Trust
35. University College London Hospitals NHS Foundation Trust
36. Imperial College Healthcare NHS Trust

When is the study starting and how long is it expected to run for?
January 2017 to November 2020

Who is funding the study?
British Neurosurgical Trainee Research Collaborative

Who is the main contact?
1. Ms Julie Woodfield
2. Dr Ingrid Hoeritzauer
3. Mr Aimun Jamjoom
4. Mr Patrick Statham

Contact information

Type(s)
Public

Contact name
Ms Julie Woodfield

Contact details
Department of Clinical Neurosciences
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Type(s)
Public

Contact name
Dr Ingrid Hoeritzauer

Contact details
Department of Clinical Neurosciences
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Type(s)
Public

Contact name
Mr Aimun Jamjoom

Contact details
Neurosurgery Department
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Type(s)
Scientific

Contact name
Mr Patrick Statham

Contact details
Department of Clinical Neurosciences
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v3

Study information

Scientific Title
Understanding cauda equina syndrome (UCES)

Acronym
UCES

Study objectives
This study aims to identify and describe the presentation and management of patients with cauda equina syndrome in the United Kingdom using trainee research collaborative networks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, 01/06/2018, IRAS Project ID: 233515, REC ref: 18/SS/0047

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cauda equina syndrome

Interventions

Patients with cauda equina syndrome will be identified on admission to spinal units across the UK and asked to participate. Data relating to presentation, hospital admission, investigations, and follow up will be collected by the local trainee investigator who is a member of the clinical team caring for the patient. Study participants who have consented to participate will also be asked to fill out details about their patient journey to the spinal unit, their symptoms, patient reported outcome measures, and service usage. These will be collected electronically anonymously via the electronic database and linked to the patient record. Patient reported outcome measures will include visual analogue scores for back and leg pain, the Oswestry Disability Index, the neurogenic bowel dysfunction score, the short form incontinence questionnaire, and the Arizona sexual experiences scale. Participants will be asked to complete questionnaires on admission, at discharge, and at six months and one year after treatment. This will provide an accurate description of the number of patients, the types of symptoms, current clinical practice, adherence to national published standards of care, and patient outcomes.

Intervention Type
Other

Primary outcome measure
The incidence of CES as measured by the number of cases of CES in the UK in all collaborating centres

Secondary outcome measures
1. The presenting symptoms and signs in patients with CES:
1.1. Back pain and leg pain measured using visual analogue scores on admission
1.2. Low back pain disability measured using Oswestry Disability Index on admission
1.3. Urinary bladder function measured using neurogenic bowel dysfunction score on admission
1.4. Urinary incontinence measured using short form incontinence questionnaire on admission
1.5. Sexual function measured using Arizona sexual experiences scale on admission
2. The pathways of presentation to specialist spinal services for patients with CES in the UK and Ireland; the type and timing of healthcare professionals seen prior to admission with the symptoms causing admission will be assessed by patient questionnaire on admission
3. The type and timing of imaging and other investigation of patients with CES, collected on admission
4. The medical and surgical management of CES, including medications, type and timing of the operation, collected from routine neurosurgical notes
5. The type and timing of investigations and surgery will be compared to the British Association of Spine Surgeons (BASS) standards of care for suspected and confirmed compressive CES issued in 2015 and the Society of British Neurological Surgeons Care Quality Statement issued in October 2015
6. Clinical outcomes for patients with CES assessed using validated patient reported outcome measures, stratified by presentation, investigations, and management:
6.1. Back pain and leg pain measured using visual analogue scores at discharge, 6 months and 1 year
6.2. Low back pain disability measured using Oswestry Disability Index 6 months and 1 year
6.3. Urinary bladder function measured using neurogenic bowel dysfunction score at discharge, 6 months and 1 year
6.4. Urinary incontinence measured using short form incontinence questionnaire at discharge, 6 months and 1 year
6.5. Sexual function measured using Arizona sexual experiences scale at discharge, 6 months and 1 year

This data and the type and timing of clinical presentation, investigation, investigation results will be analysed and stratified within one year of study completion.
7. The ability of neurosurgical and orthopaedic surgical trainee networks to collaborate successfully on a prospective cohort study, assessed at the end of the study

Overall study start date
03/01/2017

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Admitted to a specialist spinal service in the UK between 1st June 2018 and 31st May 2019
3. Capacity to provide informed consent for participation in this study
4. Diagnosis of clinical CES and structural compression of the cauda equina on imaging as determined by the treating clinician. Clinical CES includes any disturbance of saddle sensation, bladder function, bowel function, sexual dysfunction and bilateral sciatica associated with radiological compression of the cauda equina. The cauda equina compression can be due to any cause, including, but not limited to, disc, tumour, infection, etc

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Total final enrolment
659

Key exclusion criteria
1. Patients under 18 years old
2. Patients undergoing emergent decompression for unilateral motor or sensory symptoms (eg foot drop), without clinical evidence of CES
3. Patients referred with suspected CES where the diagnosis is not confirmed, for example patients with the clinical symptoms and signs of CES without radiological evidence of cauda equina compression

4. Patients not admitted to participating spinal centres in the UK
5. Patients admitted to a participating spinal centre before 1st June 2018 or after 31st May 2019
6. Patients who are unable to provide informed consent for participation in this study

Date of first enrolment
01/06/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Study participating centre
NHS Lothian
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
NHS Grampian
Aberdeen Royal Infirmary
Department of Neurosurgery
Forrester Hill
Aberdeen
United Kingdom
AB9 2ZB

Study participating centre
NHS Greater Glasgow & Clyde
Institute of Neurological Sciences
University Department of Neurosurgery
Southern General Hospital NHS Trust
Glasgow
United Kingdom
G51 4TF

Study participating centre
NHS Tayside
Ninewells Hospital And Medical School
Dept of Neurosurgery
South Block Level 6
Dundee
United Kingdom
DD1 9SY

Study participating centre
Belfast Health and Social Care Trust
Royal Victoria Hospital
Department of Neurosurgery
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Royal Victoria Infirmary
Department of Neurosurgery
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Department of Neurosurgery
Marton Road

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Department of Neurosurgery
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 4HT

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Salford Royal NHS Foundation Trust
Hope Hospital
Department of Neurosurgery
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Hull and East Yorkshire Hospitals NHS Trust
Hull Royal Infirmary
Department of Neurosurgery
Anlaby Road
Hull
United Kingdom
HU3 2KZ

Study participating centre

Leeds Teaching Hospitals NHS Trust
The General Infirmary at Leeds
Department of Neurosurgery
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Royal Hallamshire Hospital
Department of Neurosurgery
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
Nottingham University Hospitals NHS Trust
Queen's Medical Centre
Department of Neurosurgery
C Floor, West Block
University Hospital
Clifton Boulevard
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Derby Hospitals NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
University Hospital Birmingham NHS Foundation Trust
Queen Elizabeth Neuroscience Centre
Department of Neurosurgery
The Queen Elizabeth Hospital

Birmingham
United Kingdom
B15 2TH

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave Hospital
Department of Neurosurgery
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospital Southampton NHS Foundation Trust
Wessex Neurological Centre
Department of Neurosurgery
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital,
Neurosurgery Unit
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Ln
Norwich
United Kingdom
NR4 7UY

Study participating centre

East Kent Hospitals University NHS Foundation Trust
Kent and Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Oxford University Hospitals NHS Trust
Oxford Radcliffe NHS Trust
Department of Neurosurgery
Level 3, West Wing
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Ground Floor Academic Centre
Level 2, Gate 6, Brunel building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Study participating centre
Plymouth Hospitals NHS Trust
University Hospitals Plymouth NHS Trust
Department of Neurosurgery
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
North Devon District Hospital
United Kingdom
EX31 4JB

Study participating centre
Taunton and Somerset NHS Foundation Trust
Musgrove Park Hospital, Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Buckinghamshire Healthcare NHS Trust
Stoke Mandeville Hospital
Mandeville Rd
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Milton Keynes Hospital NHS Trust
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Barts Health NHS Trust
St Bartholomew's and Royal London Hospital
Department of Neurosurgery
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Barking Havering and Redbridge University Hospitals NHS Trust
Essex Neurosciences Centre
Department of Neurosurgery
Second floor, Admin Block
Queen's Hospital
Rom Valley Way

Romford
United Kingdom
RM7 0AG

Study participating centre
King’s College Hospital NHS Foundation Trust
King’s College Hospital
Department of Neurosurgery
Denmark Road
London
United Kingdom
SE5 9RS

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Hurstwood Park Neurological Centre
Department of Neurosurgery
The Princess Royal Hospital
Haywards Heath
West Sussex
United Kingdom
RH17 7RS

Study participating centre
St George’s Healthcare NHS Foundation Trust
Atkinson Morely Wing
Department of Neurosurgery
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 OQT

Study participating centre
University College London Hospitals NHS Foundation Trust
The National Hospital for Neurology & Neurosurgery
Victor Horsley Department of Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG

Study participating centre
Imperial College Healthcare NHS Trust
Charing Cross Hospital, Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor information

Organisation
NHS Lothian

Sponsor details
NHS Lothian Research & Development Office, Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Research organisation

Funder Name
British Neurosurgical Trainee Research Collaborative

Results and Publications

Publication and dissemination plan
Additional documents for this study are available on the British Neurosurgical Trainee Research Collaborative (BNTRC) website. These include study protocol, study information leaflet, participant information leaflet, GDPR information leaflet, consent form, data collection

spreadsheet, contact details. The link to these documents is: https://www.bntrc.org.uk /protocols. In addition, the study protocol has been submitted to BMJ Open for publication.

The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to investigators. Following the initial analysis and publication, study data will be made available to those who submit successful peer-reviewed proposals for use of the data to the steering committee via the BNTRC.

All local investigators who enter data for at least one case will be named as contributors on all publications arising from this study and will receive a certificate of collaboration in this study. Authorship of publications arising from this study will be determined in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
Following the initial analysis and publication, study data will be made available to those who submit successful peer-reviewed proposals for use of the data to the steering committee via the BNTRC (British Neurosurgical Trainee Research Collaborative).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/12/2018	10/12/2020	Yes	No
Other publications	Demographics of Scotland wide data	31/10/2022	02/12/2022	Yes	No
Results article		17/11/2022	02/12/2022	Yes	No
HRA research summary			28/06/2023	No	No