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Does duroplasty improve outcomes after spinal cord injury?

Submission date
18/05/2021

Recruitment status
No longer recruiting

Registration date
02/06/2021

Overall study status
Ongoing

Last Edited
09/06/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Acute traumatic spinal cord injury is a devastating condition that causes permanent disability (paralysis, numbness) and other complications such as chest and urine infections, pressure ulcers and loss of bladder and bowel control. In the UK, one person suffers a spinal cord injury every 8 hours and there are about 40,000 people living with long-term disabilities from cord injuries. Currently, there are no treatments shown to benefit patients with spinal cord injuries. After the injury, the spinal cord swells and the pressure inside the cord rises, which obstructs the flow of blood to the injury site, causing further damage. Surgery aims to straighten and fix the spine with screws and rods to reduce pressure on the injured cord. Based on our research, we think that the tough membrane around the spinal cord (dura) is a major, but unappreciated, cause of cord pressure after injury. An operation called duroplasty involves opening the dura and stitching a patch of artificial dura to expand the space around the swollen spinal cord. We have shown in a small study of patients that performing this operation safely and effectively reduces pressure on the injured cord. A similar operation is routinely used to decompress the swollen brain after brain injury, but, for spinal cord injury, standard treatment is surgery on the spine without the duroplasty. In this study, we will investigate whether duroplasty helps improve patient outcomes after spinal cord injury. We predict that patients who had standard treatment plus duroplasty will have better outcomes than those who had standard treatment alone.

Who can participate?
Adult patients (aged 16 years or older) with severe spinal cord injuries in the neck who require surgery within 72 h and agree to participate in the study. Patients with a spinal cord injury below the neck, co-existing major health conditions or co-existing medical conditions affecting the brain and/or spinal cord, and torn tough membrane around the spinal cord will not be eligible to participate.

What does the study involve?
This is a randomised controlled trial. This means that those that agree to take part will be allocated by chance (like tossing a coin) to standard treatment or standard treatment plus duroplasty. Patients will not be aware which treatment they receive. The trial aims to recruit 222 patients aged 16 years or older, with severe spinal cord injuries in the neck from 26 NHS hospitals. Consent will be obtained from the patient or their family and surgery will be done as

soon as possible (within 72 hours of injury). After agreeing to take part in the trial, patients will be asked to fill in questionnaires about their quality of life and will also be assessed on how well they can use their hands, walk and control their bladder and bowel. Some of these assessments will be repeated at 3, 6, and 12 months after surgery. These assessments will be combined with planned hospital visits and some questionnaires will be completed over the phone or by email. Some patients will also be asked to take part in a smaller study which involves placing probes at the injury site.

What are the possible benefits and risks of participating?
We cannot promise that duroplasty will help, but we predict that it will lower the build-up of damaging pressure and improve the blood flow to the spinal cord. We do not know whether this improves recovery. The trial is designed to find out whether duroplasty improves recovery after spinal cord injury or not.

There is a small risk that the duroplasty will cause spinal fluid to leak, which may need another procedure, e.g. insertion of a drain tube to the spine for a few days. Expansion duroplasty is a reconstructive operation that closes openings in the dura membrane that surrounds the spinal cord and, therefore, the risk is low.

The chance of being harmed from the probes is very low, less than 1 in 100. We know this because we have already done such recordings from many (more than 80) patients without causing damage. Nevertheless, there is a small chance that the probes cause damage to the spinal cord. The probes might get infected and the infection might spread to the spinal fluid that may need antibiotic treatment. After removing the probes, there is a small risk of a spinal fluid leak. If this happens, another small operation may be needed to stop the leak.

Where is the study run from?
The study will be managed by the Surgical Intervention Trials Unit (SITU), the University of Oxford (UK) and will be supported by the Oxford Clinical Trials Unit (OCTRU) (UK). St Georges University of London (UK) is the Study Sponsor.

When is the study starting and how long is it expected to run for?
From January 2021 to December 2026

Who is funding the study?
The National Institute for Health Research (UK) through NIHR EME, an MRC and NIHR partnership
Wings for Life

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292031

ClinicalTrials.gov (NCT)
NCT04936620

Protocol serial number
CPMS 48627, IRAS 292031 (England), IRAS 296518 (Scotland)

Study information

Scientific Title
Duroplasty for Injured cervical Spinal Cord with Uncontrolled Swelling (DISCUS)

Acronym
DISCUS

Study objectives

After traumatic spinal cord injury, the spinal cord swells and becomes compressed against the dura.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 24/05/2021, England- London- Camberwell St Giles Research Ethic Committee (Ground Floor Temple Quay House, 2 The Square, Bristol BS1 6PN; +44 (0)207 104 8138, +44 (0) 207 104 8340, +44 (0)207 104 8089; camberwellstgiles.rec@hra.nhs.uk)
2. Approved 23/06/2021, Scotland A Research Ethics Committee (Ethics Department, 2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG; +44 (0)131465 5680; Manx. Neill@nhslothian.scot.nhs.uk)

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traumatic Spinal Cord Injury (TSCI)

Interventions
Randomised trial: The control arm is surgery including laminectomy. The intervention arm is surgery including laminectomy and duroplasty. Duroplasty takes 10-15 min during the operation. The control/intervention surgeries will be done within 72 h of injury.

Mechanistic study: Insertion of pressure probe and/or microdialysis catheter intradurally at the injury site. This is optional and is done during the surgical procedure. The probes are left in for a maximum of 5 days.

All patients will be followed up for 6 months and 1 year after randomisation.

Patients will be randomised 1:1 to one of the two trial arms. The allocation to treatment options will use a web based secure randomisation system (RRAMP) using minimisation algorithm (age and country).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Functional impairment measured using the American Spinal Injury Association Impairment Scale total limb motor score at baseline and 6 months

Key secondary outcome(s))

Phase III trial:
1. Light-touch sensory impairment measured using the American Spinal Injury Association Impairment Scale total light touch sensory score at baseline and 6 months
2. Pin prick sensory impairment measured using the American Spinal Injury Association Impairment Scale total pin prick sensory scoreat baseline and 6 months
3. Functional impairment in American Spinal Injury Association grade at baseline and 6 months
4. Upper extremity function measured using the Capabilities of Upper Extremity-Questionnaire (CUE-Q) at 6 months
5. Hand grip strength measured using a dynamometer at 6 months
6. Walking ability measured using Walking Index for Spinal Cord Injury version ii (WISCI II) at 6 months
7. Independence in activities of daily living measured using Spinal Cord Independence Measure version iii (SCIM III) at 6 months
8. Health status measured using the Short Form survey (SF-36) at 3, 6, and 12 months
9. Number of reoperations on spine measured from patient records at 12 months
10. Procedure Specific complications and adverse events measured from patient records at 12 months
11. Mortality measured from patient records at 12 months
12. Length of hospital stay measured from patient records at 12 months
13. Spinal deformity (Cobb angle), length of tethered cord, and size of syrinx measured using magnetic resonance imaging (MRI) at 6 months

Optional mechanistic study:
1. Mean daily intraspinal pressure measured using a pressure probe at the injury site for up to 5 days after surgery
2. Spinal cord perfusion pressure measured using a pressure probe at the injury site for up to 5 days after surgery
3. Tissue glucose, lactate, pyruvate, glycerol, glutamate, and cytokines measured using an intradural microdialysis catheter at the injury site for up to 5 days after surgery

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Age ≥16 years
2. Severe cervical (C2 – T1) traumatic spinal cord injury (AIS grade A–C)
3. Deemed to require and be suitable for surgery that includes laminectomy by local surgeon
4. Surgery within 72 h of traumatic spinal cord injury (TSCI)
5. Able to provide informed consent or proxy consent or consent/declaration provided by consultee, nearest relative/guardian/welfare attorney

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Dural tear due to traumatic spinal cord injury (TSCI)
2. Life-limiting or rehabilitation-restricting co-morbidities
3. Thoracic or lumbar traumatic spinal cord injury
4. Other central nervous system disease

Date of first enrolment
08/10/2021

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Austria

Belgium

Denmark

Germany

Israel

Slovenia

Spain

Sweden

Study participating centre
St George’s University Hospitals NHS Foundation Trust
St George’s Hospital
Blackshaw Road

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Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
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Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
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E1 2ES

Study participating centre
King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
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United Kingdom
SE5 9RS

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary

Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
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B15 2GW

Study participating centre
Salford Royal NHS Foundation Trust
Salford Royal
Stott Lane
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United Kingdom
M6 8HD

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
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United Kingdom
AB15 6RE

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House

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1055 Great Western Road
Glasgow
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G12 0XH

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NHS Lothian
Waverley Gate
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Great George Street
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The Walton Centre NHS Foundation Trust
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Study participating centre
Imperial College Healthcare NHS Trust
The Bays
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Study participating centre
Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital

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WF1 4DG

Study participating centre
Southport And Ormskirk Hospital NHS Trust
Town Lane
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PR8 6PN

Study participating centre
The Robert Jones And Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
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SY10 7AG

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
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HA7 4LP

Study participating centre
Shaare Zedek Medical Centre
Jerusalem
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-

Study participating centre
Aarhus University Hospital
Aarhus
Denmark
-

Study participating centre

Salzburg University Hospital
Salzburg
Austria
-

Study participating centre
Skåne University Hospital
Skåne
Sweden
-

Study participating centre
UZ Leuven
Leuven
Belgium
-

Study participating centre
Kepler University Hospital
-
Austria
-

Study participating centre
Hadassah Medical Centre
Jerusalem
Israel
-

Study participating centre
12 de Octubre Hospital
Spain
-

Study participating centre
BG Unfallklinik Frankfurt am Main
Frankfurt
Germany
-

Study participating centre
University Medical Centre Ljubljana
Ljubljana
Slovenia
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Study participating centre
Innsbruck University Hospital
Innsbruck
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Sponsor information

Organisation
St George's, University of London

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Funder Name
Wings for Life

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/08/2023	09/08/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes