ISRCTN57142415 https://doi.org/10.1186/ISRCTN57142415

Cerebrospinal fluid shunting or dural venous sinus stenting to preserve vision in idiopathic intracranial hypertension (IIH Intervention)

Submission date
10/11/2022

Recruitment status
Recruiting

Registration date
02/02/2023

Overall study status
Ongoing

Last Edited
01/04/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Idiopathic intracranial hypertension (IIH) is a neurological condition characterised by increased pressure inside the skull, called intracranial pressure (ICP). It is more common in women of reproductive age with obesity. Common symptoms of IIH include headaches, blurred vision and ringing in the ears. If left untreated, the disorder may cause blindness. The majority of patients with IIH are managed with weight loss and medications. Fewer than 10% of patients develop progressive visual loss and require urgent intervention to reduce ICP and preserve vision. This trial will compare the two most common interventions performed in the UK and evaluate their clinical and cost-effectiveness. The first is called cerebrospinal fluid (CSF) shunting and involves a procedure where a thin tube called a shunt is implanted in the body to drain brain fluid. The second is called dural venous sinus stenting (DVSS) and involves a procedure where a metallic mesh tube called a stent is implanted inside a brain blood vessel. Both procedures can preserve vision, but there is no strong evidence to support one over the other. Participants will have the same chance to be treated with CSF shunting or DVSS. The aim of the trial is to know which intervention is the most effective to save the vision and the most cost-effective.

Who can participate?
Adults with a diagnosis of IIH at risk of permanent sight loss

What does the study involve?
The trial will be conducted in NHS hospitals located in England, Wales and Scotland. Participants are randomly allocated to undergo cerebrospinal fluid (CSF) shunting or dural venous sinus stenting (DVSS). Afterwards the participants will be asked to attend 11 hospital appointments and one telephone appointment. This follow-up will take 2 years from start to finish. Participants will be closely monitored for any side effects and potential device failure, and for changes in vision, headaches and quality of life. The researchers will also collect health data from NHS Digital (the national custodian of NHS health and social care data).

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the trial but the information gained from this

trial may help improve treatment for adults with IIH in the future. Participants may be seen more often and/or feel more supported as a consequence of their involvement in the trial. As with any intervention, there are risks and complications, but there are no additional disadvantages or risks involved in taking part in this trial. Both CSF shunting and stenting are treatments for IIH (shunting is widely used internationally, and in some hospitals, stenting is used as part of the standard of care). Participants require an intervention to prevent sight loss. None of these treatments is experimental but at present, there is not enough information to determine which treatment is most suitable and provides the higher level of health benefits to the individual.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2021 to February 2029

Who is funding the study?
National Institute for Health Research (NIHR, grant number: NIHR131211) (UK)

Who is the main contact?
IIH Intervention Trial manager, IIHIntervention@trials.bham.ac.uk (UK)

Contact information

Type(s)
Public

Contact name
None - IIH Intervention Trial Office

Contact details
D3B Clinical Trial Team
5th Floor
Open Plan East
Institute of Translational Medicine
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH
-
IIHIntervention@trials.bham.ac.uk

Type(s)
Scientific

Contact name
Mr Darren Barton

ORCID ID
https://orcid.org/0000-0003-0106-5861

Contact details

D3B clinical trial team
Office 15, 5th Floor
Open Plan EAST, ITM
Heritage Building
Mindelson Way
Edgbaston
Birmingham
United Kingdom
B15 2TH
+44 (0)121 371 8027
IIHIntervention@trials.bham.ac.uk

Additional identifiers

Central Portfolio Management System (CPMS)
54221

Integrated Research Application System (IRAS)
314408

Study information

Scientific Title
Intervention to preserve vision in idiopathic intracranial hypertension: evaluation of clinical effectiveness and cost-effectiveness

Study objectives
Current study objectives as of 31/03/2026:

The primary objective is to compare DVSS with CSF shunting in terms of effectiveness to reduce papilloedema by change in global thickness of the retinal nerve fibre layer (RNFL) measured by optical coherence tomography (OCT) over 6 months.

———

Previous study objectives:

To ascertain if the progression of visual function over 12 months, as measured by perimetric mean deviation, differs for idiopathic intracranial hypertension patients (IIH) undergoing dural venous sinus stenting compared to IIH patients undergoing cerebrospinal fluid shunting

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/12/2022, West Midlands - South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; no telephone number provided; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0230

Study design

Randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Idiopathic intracranial hypertension

Interventions
Current interventions as of 31/03/2026:

Participants are randomized to undergo either cerebrospinal fluid (CSF) shunting or dural venous sinus stenting (DVSS).

The null hypothesis, which the researchers aim to disprove, is that dural venous sinus stenting (DVSS) is equivalent to cerebrospinal fluid (CSF) shunting in terms of the long-term trajectory of reducing papilloedema preventing visual loss during the treatment of idiopathic intracranial hypertension (IIH). CSF shunting represents the standard of care treatment for these patients and so makes the natural comparator. The secondary and exploratory outcomes will help the researchers to ascertain how these treatments affect different parts of the lives of patients with IIH.

The researchers have chosen a randomized design (randomized 1:1) to provide an unbiased comparison and to avoid the potential confounding factors implicit in non-randomised comparisons.

Once a potential participant has completed the screening process and is deemed eligible for study inclusion, they will be randomized on a 1:1 basis using computer-generated randomization via the Trial eRDC system. Patient treatment allocation will be stratified by the following criteria:
1. Presence of or intention to insert CSF lumbar drain prior to the protocol-defined intervention
2. Duration of IIH diagnosis (diagnosis ≤28 days from randomisation or diagnosis >28 days from randomisation)
3. The degree of papilloedema defined by the Frisén grade being <4 or ≥4 in the most affected study eye

To avoid any possibility of the treatment allocation becoming too predictable, a random factor will be included within the algorithm whereby for a proportion of the allocations true randomisation will be implemented rather than by using the minimisation allocation. 80% of randomisations will be ascertained using the minimisation allocation, with the remaining 20% being true randomisation. In this manner the local responsible clinician will not be able to predict or influence the treatment allocation.

———

Previous interventions:

Participants are randomized to undergo either cerebrospinal fluid (CSF) shunting or dural venous sinus stenting (DVSS).

The null hypothesis, which the researchers aim to disprove, is that dural venous sinus stenting (DVSS) is equivalent to cerebrospinal fluid (CSF) shunting in terms of the long-term trajectory of perimetric mean deviation for the treatment of idiopathic intracranial hypertension (IIH). CSF shunting represents the standard of care treatment for these patients and so makes the natural comparator. The secondary and exploratory outcomes will help the researchers to ascertain how these treatments affect different parts of the lives of patients with IIH.

The researchers have chosen a randomized design (randomized 1:1) to provide an unbiased comparison and to avoid the potential confounding factors implicit in non-randomised comparisons.

Once a potential participant has completed the screening process and is deemed eligible for study inclusion, they will be randomized on a 1:1 basis using computer-generated randomization via the Trial eRDC system. Patient treatment allocation will be stratified by the following criteria:
1. Presence of or intention to insert CSF lumbar drain prior to the protocol-defined intervention
2. Duration of IIH diagnosis (diagnosis ≤28 days from randomisation or diagnosis >28 days from randomisation)
3. The degree of papilloedema defined by the Frisén grade being <4 or ≥4 in the most affected study eye

To avoid any possibility of the treatment allocation becoming too predictable, a random factor will be included within the algorithm whereby for a proportion of the allocations true randomisation will be implemented rather than by using the minimisation allocation. 80% of randomisations will be ascertained using the minimisation allocation, with the remaining 20% being true randomisation. In this manner the local responsible clinician will not be able to predict or influence the treatment allocation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome(s) as of 31/03/2026:

Global thickness of the retinal nerve fibre layer (RNFL) over 6 months, as measured by OCT (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, and 6 months post-intervention, and at any unscheduled visit for revision /device failure between Visit 2 and 6 months post-intervention.

———

Previous primary outcome(s):

Perimetric mean deviation (PMD) is measured using a Humphrey Visual Field (HVF) over 12 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6 and 12 months post-intervention, and at any unscheduled visit for revision/device failure between Visit 2 and 12 months post-intervention.

Key secondary outcome(s))
Current key secondary outcome(s) as of 31/03/2026:

Secondary outcome measures have been listed by category for clarity. Analysis will be over the time period stated (analysed using repeated measures methods). The primary efficacy analysis

will use an interval of baseline to 6 months (analysis occurring once the final patient has completed their 6-month assessment) with longer-term follow-up using an interval of baseline to 12 months (occurring once the final patient has completed their 12-month assessment). and baseline to 24 months (occurring once the final patient has completed their 24-month assessment).

Vision:
1. Global thickness of the retinal nerve fibre layer (RNFL) over 12 and 24 months (analysed using repeated measures methods) using data collected at 12 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
2. Total retinal thickness measured using Optical Coherence Tomography (OCT) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
3. Disc global volume measured using Optical Coherence Tomography (OCT) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
4. Disc central thickness measured using Optical Coherence Tomography (OCT) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
5. Disc maximum height measured using Optical Coherence Tomography (OCT) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
6. Visual acuity is measured by logarithm of the minimum angle or resolution (LogMAR) units over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
7. Perimetric mean deviation (PMD) measured by Humphrey Visual Field over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.

Intervention reporting:
1. Proportion of patients representing to hospital within 30 days of primary trial intervention, calculated as the percentage of patients who present over all patients in the arm and will be measured at 1 week, 2 weeks and 1 month, and at any unscheduled visit for revision/device failure during that period.
2. Proportion of patients being re-admitted to hospital within 30 days of primary trial intervention, calculated as the percentage of patients who are re-admitted over all patients in the arm and will be measured at 1 week, 2 weeks and 1 month, and at any unscheduled visit for revision/device failure during that period.
3. Proportion of major complication, defined as the incidence of complications graded between III and V or major anaesthesia problems (including complications from revision procedures) according to the Clavien-Dindo classification of surgical complications reported at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, and 12 months post-intervention, and at any unscheduled visit for revision/device failure between Visit 2 and 12 months post-intervention.
4. Proportion of major complication, defined as the incidence of complications graded between III and V or major anaesthesia problems (including complications from revision procedures) according to the Clavien-Dindo classification of surgical complications reported at intervention,

and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
5. Proportion with minor complications, defined as Clavien-Dindo grade I-II during hospital stay, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6 and 12 months post-intervention, and at any unscheduled visit for revision/device failure between Visit 2 and 12-month post-intervention.
6. Proportion with minor complications, defined as Clavien-Dindo grade I-II during hospital stay, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
7. Proportion of patients requiring revision in whom the revision intervention is the same as the primary intervention over 12 and 24 months post-intervention, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
8. Proportion of patients requiring revision in whom the revision intervention crosses over to the alternative intervention over 6, 12 and 24 months post-intervention, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
9. Time to first revision measured as the average number of days between primary trial intervention and first revision over 6, 12 and 24 months, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
10. Number of revisions per patient as captured on an unscheduled revision CRF and/or a valve adjustment CRF over 6, 12 and 24 months. Data pertinent for this outcome may be completed anytime from the time of intervention, to 24 months post-intervention (including 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure).
11. Proportion of patients with adverse events as measured by the CTCAE version 5 at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.

Headache:
1. Monthly headache days (MHD) in a 28-day period over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline/screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
2. Headache severity measured by numeric rating scale 0-10, where 10 is the worst pain, in a 28-day period over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline/screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
3. Monthly moderate to severe headache days, defined as the number of days when the headache is moderate to severe in intensity (numeric rating scale scores of 4-10), and lasts for more than 4 hours or that requires acute headache analgesia, in a 28-day period over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline /screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
4. Moderate to severe headache severity measured by NRS (NRS ≥ 4) in a 28-day period over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline /screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
5. Monthly use of acute headache analgesics calculated in 28-day periods over 6, 12 and 24 months (analysed using repeated measures methods) from reported concomitant medications at baseline, intervention visit, 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.

Patient-Reported Outcome Measures (PROM):
1. Quality of recovery is measured using the Quality of Recovery 15 questionnaire (QoR-15) at time of discharge
2. Satisfaction with intervention is measured using a 5-point Likert scale at time of discharge
3. Visual function is measured using the Visual Function Questionnaire (NEI-VFQ-25) with 10-Item Neuro-Ophthalmic Supplement) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, intervention visit, 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
4. Headache disability is measured using the Headache Impact Test (HIT-6) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
5. Health status is measured using the 36-item Short form health survey (version 2, SF-36v2) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
6. Health-related utility values measured using the EuroQol 5 dimension 5 level (EQ5D-5L) instrument over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1 week, 2 weeks, 1, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
7. Time to return to work (if working) measured by a study-specific question added to the Work Productivity and Activity Impairment Questionnaire – General Health (WPAI-GH) over 24 months (analysed using repeated measures methods) using data collected at baseline, 2, 6, 12, 18 and 24 months post-intervention.
8. Impairments in work and activities are measured using the Work Productivity and Activity Impairment Questionnaire – General Health (WPAI–GH) over 6, 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 2, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
9. Healthcare resource use over 6, 12 and 24 months, measured using a study-specific questionnaire at baseline, 1 week, 2 weeks, 1, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.

———

Previous key secondary outcome(s):

Secondary outcome measures have been listed by category for clarity. Analysis will be over the time period stated (analysed using repeated measures methods). The primary efficacy analysis will use an interval of baseline to 12 months (analysis occurring once the final patient has completed their 12-month assessment) with longer-term follow-up using an interval of baseline to 24 months (occurring once the final patient has completed their 24-month assessment).

Vision:
1. Perimetric mean deviation (PMD) is measured by Humphrey Visual Field (HVF) over 24 months (analysed using repeated measures methods) using data collected at 24 months post-intervention, and at any unscheduled visit for revision/device failure.
2. Retinal nerve fibre layer (RNFL) thickness is measured using Optical Coherence Tomography (OCT) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the

latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
3. Optic nerve head size is measured using Optical Coherence Tomography (OCT) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
4. Macular ganglion cell layer/complex thickness is measured using Optical Coherence Tomography (OCT) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.
5. Visual acuity is measured by logarithm of the minimum angle or resolution (LogMAR) units over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12 and 24 months post-intervention (the latter only pertinent to the 24-month analyses), and at any unscheduled visit for revision/device failure.

Intervention reporting:
1. Proportion of patients representing to hospital within 30 days of primary trial intervention, calculated as the percentage of patients who present over all patients in the arm and will be measured at 1 week, 2 weeks and 1 month, and at any unscheduled visit for revision/device failure during that period.
2. Proportion of patients being re-admitted to hospital within 30 days of primary trial intervention, calculated as the percentage of patients who are re-admitted over all patients in the arm and will be measured at 1 week, 2 weeks and 1 month, and at any unscheduled visit for revision/device failure during that period.
3. Proportion of major complication, defined as the incidence of complications graded between III and V or major anaesthesia problems (including complications from revision procedures) according to the Clavien-Dindo classification of surgical complications reported at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, and 12 months post-intervention, and at any unscheduled visit for revision/device failure between Visit 2 and 12 months post-intervention.
4. Proportion of major complication, defined as the incidence of complications graded between III and V or major anaesthesia problems (including complications from revision procedures) according to the Clavien-Dindo classification of surgical complications reported at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
5. Proportion with minor complications, defined as Clavien-Dindo grade I-II during hospital stay, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6 and 12 months post-intervention, and at any unscheduled visit for revision/device failure between Visit 2 and 12-month post-intervention.
6. Proportion with minor complications, defined as Clavien-Dindo grade I-II during hospital stay, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
7. Proportion of patients requiring revision in whom the revision intervention is the same as the primary intervention over 12 and 24 months post-intervention, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
8. Proportion of patients requiring revision in whom the revision intervention crosses over to the alternative intervention over 12 and 24 months post-intervention, measured at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
9. Time to first revision measured as the average number of days between primary trial intervention and first revision over 12 and 24 months, measured at intervention, and then 1

week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
10. Number of revisions per patient as captured on an unscheduled revision CRF and/or a valve adjustment CRF over 12 and 24 months. Data pertinent for this outcome may be completed anytime from the time of intervention, to 24 months post-intervention (including 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure).
11. Proportion of patients with adverse events as measured by the CTCAE version 5 at intervention, and then 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.

Headache:
1. Monthly headache days (MHD) in a 28-day period over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline/screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
2. Headache severity measured by numeric rating scale 0-10, where 10 is the worst pain, in a 28-day period over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline/screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
3. Monthly moderate to severe headache days, defined as the number of days when the headache is moderate to severe in intensity (numeric rating scale scores of 4-10), and lasts for more than 4 hours or that requires acute headache analgesia, in a 28-day period over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline/screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision /device failure.
4. Moderate to severe headache severity measured by NRS (NRS ≥ 4) in a 28-day period over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline /screening, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
5. Monthly use of acute headache analgesics calculated in 28-day periods over 12 and 24 months (analysed using repeated measures methods) from reported concomitant medications at baseline, intervention visit, 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.

Patient-Reported Outcome Measures (PROM):
1. Quality of recovery is measured using the Quality of Recovery 15 questionnaire (QoR-15) at time of discharge
2. Satisfaction with intervention is measured using a 5-point Likert scale at time of discharge
3. Visual function is measured using the Visual Function Questionnaire (NEI-VFQ-25) with 10-Item Neuro-Ophthalmic Supplement) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, intervention visit, 1 week, 2 weeks, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
4. Headache disability is measured using the Headache Impact Test (HIT-6) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
5. Health status is measured using the 36-item Short form health survey (version 2, SF-36v2) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1, 2, 3, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision /device failure if not completed in the previous 8 weeks.
6. Health-related utility values measured using the EuroQol 5 dimension 5 level (EQ5D-5L)

instrument over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 1 week, 2 weeks, 1, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure.
7. Time to return to work (if working) measured by a study-specific question added to the Work Productivity and Activity Impairment Questionnaire – General Health (WPAI-GH) over 24 months (analysed using repeated measures methods) using data collected at baseline, 2, 6, 12, 18 and 24 months post-intervention.
8. Impairments in work and activities are measured using the Work Productivity and Activity Impairment Questionnaire – General Health (WPAI–GH) over 12 and 24 months (analysed using repeated measures methods) using data collected at baseline, 2, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.
9. Healthcare resource use over 12 and 24 months, measured using a study-specific questionnaire at baseline, 1 week, 2 weeks, 1, 4, 6, 12, 18 and 24 months post-intervention, and at any unscheduled visit for revision/device failure if not completed in the previous 8 weeks.

Completion date
28/02/2029

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 31/03/2026:

1. Diagnosis of IIH by the IIH consensus guidelines with papilloedema and at risk of visual loss
2. Presence of papilloedema (Frisén grade ≥ 3) in at least one eye
3. Age 18 to < 64 years at the time of consent
4. Patients must be suitable for and willing to proceed with both CSF shunting (VP or Lumboperitoneal shunts only) and DVSS.
5. Able to provide written informed consent

———

Previous key inclusion criteria:

List of principal criteria:
1. Diagnosis of idiopathic intracranial hypertension (IIH) by the IIH consensus guideline with bilateral papilloedema and a risk of permanent visual loss
2. Visual loss in at least one eye (study eye), secondary to papilloedema that cannot be explained by other ocular or central nervous system (CNS) pathology
3. Participants will be suitable for both cerebrospinal fluid (CSF) shunting and dural venous sinus stenting (DVSS)
4. Age 18 to <64 years at the time of consent
5. Able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 31/03/2026:

1. Presence of current venous sinus thrombosis on diagnostic brain imaging by either MRI, MRV or CTV
2. Previous surgery for IIH including, optic nerve sheath fenestration, CSF shunting procedures, sub-temporal decompression and DVSS.
3. Previous bariatric surgery within the last 3 months
4. Patients with a past ophthalmic history, except refraction error, affecting the eligible eyes (study eyes) that could affect the vision.
5. Patient is, at the time of signing the informed consent, a user of recreational or illicit drugs (including marijuana) or has had a recent history (within the last year) of drug or alcohol abuse or dependence, in the opinion of the investigator.
6. History of any clinically significant disease or disorder which, in the opinion of the investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject's ability to participate in the study.
7. Have participated in any other interventional study within 30 days prior to the screening visit (of note participation in the IIH Life database or other observational studies will not prevent enrolment to this study).
8. Previous randomisation for treatment in the present study.
9. Pregnant.
10. Absolute or serious contraindication to standard anti-thrombotic regimen peri and post stenting.
11. Secondary causes of raised intracranial pressure1. (Refer to protocol appendix 3 for additional information.)
12. History of significant documented iodine-based contrast allergy.
13. History of documented allergy to nitinol or nickel.
14. Absolute or serious contraindication for general anaesthesia.
15. Previous diagnosis of a hypercoagulable state (Factor V Leiden, Protein C or S deficiency, Anticardiolipin antibodies, Lupus anticoagulant, B2-glycoprotein-1 antibodies, or Hyperhomocysteinaemia).
16. Currently requiring full anticoagulation for other medical reasons, such as atrial fibrillation, artificial valves, deep vein thrombosis or pulmonary embolism.
17. Documented prior non-traumatic intracranial haemorrhage.
18. History of deep vein thrombosis or pulmonary embolism (within the last 24 months).
19. History of severe carotid atherosclerotic disease.

20. History of heart failure, dilated cardiomyopathy or congenital heart disease, etc. that are assessed as at high thrombotic risk.

_____

Previous key exclusion criteria:

List of principal criteria:
1. Presence of current venous sinus thrombosis on diagnostic brain imaging by either Magnetic Resonance Imaging (MRI), Magnetic Resonance Venography (MRV) or Computed Tomography Venography (CTV)
2. A completely normal CTV (or MRV) with clear visualisation of the whole sinus with no evidence of stenosis(es)
3. Previous surgery for IIH including, optic nerve sheath fenestration, CSF shunting procedures, sub-temporal decompression and DVSS.
4. Previous bariatric surgery within the last 3 months
5. Patients with a past ophthalmic history affecting the eligible eye(s) that could affect the vision (e.g. prior optic atrophy)
6. History of any clinically significant disease or disorder which, in the opinion of the investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject's ability to participate in the study
7. Have participated in any other interventional study within 1 month prior to the screening visit (of note participation in the IIH Life database or other observational studies will not prevent enrolment in this study)
8. Previous randomisation for treatment in the present study
9. Pregnant
10. Absolute or serious contraindication to standard anti-thrombotic regimen peri- and post-stenting
11. Other secondary causes of raised intracranial pressure, including: haematological (e.g. moderate to severe anaemia); causes of venous obstruction (e.g. cerebral venous sinus thrombosis); medications (e.g. quinolones); systemic disorders (e.g. chronic kidney disease); endocrine (e.g. Addison's disease); and syndromic (See Protocol Appendix 3 for a full list)
12. Absolute or serious contraindication for general anaesthesia

Date of first enrolment
22/11/2023

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
England
LS1 3EX

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road

Newcastle upon Tyne
England
TS1 4LP

Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
London
England
WC1N 3BG

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Sunderland Eye Infirmary
Queen Alexandra Road
Sunderland
England
SR2 9HP

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Princess Alexandra Eye Pavillion
45 Chalmers Street
Edinburgh
Lothian
Scotland
EH3 9HA

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the CRUK clinical trials unit in accordance with the CRCTU data-sharing policy: https://www.birmingham.ac.uk/research/crctu/Data-sharing-policy.aspx. Any request to access clinical trial data needs to be requested in writing via the CRCTU data-sharing request form. These data will only be made available after the full analysis of the study data has been undertaken and published in addition to the generation of a complete study report.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	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