ISRCTN13784335 https://doi.org/10.1186/ISRCTN13784335

Stenting of venous sinus stenosis for medically refractory idiopathic intracranial hypertension

Submission date
01/05/2015

Recruitment status
No longer recruiting

Registration date
13/08/2015

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Intracranial hypertension (IH) describes abnormally high pressure inside the skull. Symptoms of IH include severe throbbing headaches that are worse in the morning and changes in vision. There are various recognised causes of IH, such as a brain tumour or brain infection. Sometimes there is no obvious cause of IH, and in these instances it is described as idiopathic intracranial hypertension (IIH). Severe narrowing (stenosis) of the vein (transverse-sigmoid) sinuses on both sides of the head has been recognised as a potential cause of IIH. One way to treat narrow vein sinuses in IIH is to surgically insert stents into them. A stent is a small mesh tube that is often used to widen narrow blood vessels, such as arteries. Stenting in IIH may help normalise the pressure of cerebrospinal fluid (CSF), the liquid which fills and surrounds the brain. Normalisation of CSF may help reduce the visual symptoms and headaches associated with IIH in patients. The aim of this study is to see how effective and safe venous sinus stenting is in patients that have not responded to other types of treatment for IIH.

Who can participate?
Adults diagnosed with IIH.

What does the study involve?
All participants have venous sinus stenting surgery. Participants complete questionnaires and attend follow up 1 month after treatment, then again at 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Research studies such as this are performed to determine how safe and effective a specific medical treatment or device is. No direct benefit to participants can be guaranteed. The risks associated with the stent procedure (including those associated with the cerebral angiogram) include transient neurological deficit, permanent neurological deficit (or stroke), hearing loss, unsteadiness, cerebral bleeding, death, contrast material (X-ray dye) or drug allergic reaction, kidney failure, infection, cerebral venous stroke or blockage to the artery in the leg requiring surgical repair or the need for blood transfusion. All risks will be fully discussed with participants.

Where is the study run from?
Hospital Center University of Quebec - Hospital of the Child Jesus (CHU de Québec - Hôpital de l'Enfant-Jésus) (Canada)

When is the study starting and how long is it expected to run for?
September 2010 to January 2015

Who is funding the study?
1. Canadian Heads of Academic Radiology/GE Healthcare Development Program (Canada)
2. Laval University - Department of Medical Imaging (Université Laval) (Canada)

Who is the main contact?
Dr P Lavoie

Contact information

Type(s)
Scientific

Contact name
Dr Pascale Lavoie

Contact details
Hôpital de l'Enfant-Jésus
Département des Sciences neurologiques
1401 18e rue
Québec (QC)
Canada
G1J 1Z4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012-1482

Study information

Scientific Title
Stenting of venous sinus stenosis for medically refractory idiopathic intracranial hypertension: a cohort study

Study objectives
Severe bilateral stenosis of the transverse-sigmoid sinuses has been recognised as a potential etiology of idiopathic intracranial hypertension (IIH). The treatment and prevention of these

stenosis by venous sinus stenting may be effective in normalising the cerebrospinal fluid (CSF) pressure, reducing visual symptoms and headaches in patients with IIH refractory to other treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hospital Center University of Quebec (Centre Hospitalier Universitaire (CHU) de Québec), 12/01/2011, ref: 2012-1482, PEJ-578.

Study design
Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Idiopathic intracranial hypertension

Interventions
Endovascular venous sinus stenting.

Intervention Type
Procedure/Surgery

Primary outcome measure
CSF pressure normalisation at 6 months follow up. CSF pressure will be measured by lumbar puncture at the start of the trial and 6 months after the stenting. A normalisation is defined as at least a 15 mmHg difference between pre- and post-op lumbar puncture.

Secondary outcome measures
1. Significant decrease in CSF pressure at 6 months
2. Improvement of visual fields, visual acuity, vision color, visual evoked potential at 3 months and 12 months
3. Improvement of papilloedema (according to Frisén scale) at 3 months and absence of papilloedema at 12 months, with improvement of OCT
4. Resolution of visual complaints (transient visual losses, visual obscurations, poor vision,

blurring of vision etc.) at 12 months
5. Decrease of headaches score (HIT-6) and severity at 12 months
6. Improvement in Quality of Life at 12 months
7. 12 months stent patency on CT-Venous angiogram
8. Safety and treatment side effects immediately after intervention and at 1 month (evaluated in neurology), and modified Rankin scale immediately after intervention and at 1 month.

Overall study start date
01/09/2010

Completion date
05/01/2015

Eligibility

Key inclusion criteria
1. Patients aged 18 and over with diagnosis of IIH according to Friedman diagnostic criteria for whom standard medical treatment has failed (defined as persistent headaches or visual symptoms or papilloedema in spite of 3 months treatment with Diamox or intolerance of side effect of the medication)
2.Venous imaging (CT, MR or standard venography) showing bilateral transverse sinus stenoses or unilateral transverse sinus stenosis with contralateral transverse sinus atresia. At least one of the stenosis must cause >50% reduction of the sinus lumen.
3. Pressure gradient across the stenosis >8 mmHg
4. Signed informed consent obtained from the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
33

Key exclusion criteria
1. Allergic reaction to iodine contrast despite premedication
2. Contraindication to general anaesthesia
3. Contraindication to aspirin, Clopidogrel (Plavix®) or anticoagulants
4. Patient with medical history of intracranial venous thrombosis (which do not correspond to idiopathic intracranial hypertension and increase risk of venous stent thrombosis)
5. Pregnant women

Date of first enrolment

20/09/2011

Date of final enrolment
12/03/2014

Locations

Countries of recruitment
Canada

Study participating centre
Hospital Center University of Quebec - Hospital of the Child Jesus (CHU de Québec - Hôpital de l'Enfant-Jésus)
1401 18E street
Québec
Canada
G1J 1Z4

Sponsor information

Organisation
CHU de Québec

Sponsor details
1401 18E rue
Québec (QC)
Canada
G1J 1Z4

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/006a7pj43

Funder(s)

Funder type
Other

Funder Name
Canadian Heads of Academic Radiology/GE Healthcare Development Program (Canada)

Funder Name
Laval University - Department of Medical Imaging (Université Laval) (Canada)

Results and Publications

Publication and dissemination plan
An article will be submitted to Stroke journal and the results will be presented at a national conference such as The Canadian Society for Neurological Sciences.

Intention to publish date
01/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	adverse event report	01/02/2018	17/12/2020	Yes	No