RANDOMISED **E**VALUATION OF **V**ENOUS **I**NTERVENTION VERSUS **S**HUNTING IN **I**IH WITH **O**PTIC **N**ERVE SWELLING (**REVISION**)

Rationale:

Medically refractory IIH is a significant clinical burden with affected individuals suffering from significant morbidity with chronic disabling headaches, together with progressive visual loss, which is severe and permanent in up to 25% of cases. Although traditionally treated with CSF diversion procedures there is a high rate of shunt failure (approximately 30% within 12 months) with significant impact on quality of life.

In recent years with increased understanding of the pathophysiology of IIH, and recognition of the frequency of venous sinus stenosis in these patients, venous sinus stenting has emerged as a viable alternative treatment option for IIH. It has a high technical success rate with a low level of complications.

Throughout the UK, and in fact the rest of the world, the most appropriate surgical treatment of fulminant IIH is unclear. In fact, between neurosurgical units, significant discrepancy exists in the surgical treatment offered and even that available.

A Cochrane review in 2005, which was updated in 2009 and subsequently in 2014, has confirmed the lack of randomised controlled trials in the treatment options for IIH.

A multi-centre, superiority, pragmatic, randomised trial of stenting versus CSF diversion has the potential to provide definitive evidence regarding the comparative clinical and cost effectiveness of these procedures, thus providing the drive to standardise treatment for these patients.

Research Question

Is venous stenting more clinically and/or cost effective than CSF shunting procedures for medically refractory idiopathic intracranial hypertension?

1. **Intervention:** Cerebral venous sinus stenting
2. **Patient group:** Adults with medically refractory idiopathic intracranial hypertension (IIH)
3. **Setting:** Secondary care
4. **Control:** Ventriculoperitoneal shunting (or other CSF diversion procedure)
5. **Study design:** Randomised controlled trial
6. **Important outcomes:** Objective improvement in IIH symptoms and signs (e.g. headache, papilloedema and visual fields); QoL, number of infections & repeat IIH-related surgeries;
7. **Minimum duration of follow-up:** 24 months

Proposed Study Setting:

Tertiary care UK hospitals with access to both venous sinus stenting and CSF diversion procedures

Recruitment target: 150 patients

Target Population: Patients with medically refractory IIH, referred to a neurosurgical unit where there is access to both interventions and the treating Consultant is in clinical equipoise and both patient and Consultant are committed to intervention.

Inclusion criteria

1. Age >18 yrs.
2. Medically refractory IIH with visual decline; or non-compliance / unable to tolerate maximum therapy
3. CT Venogram demonstrating venous sinus narrowing
4. Venous sinus pressure gradient across the narrowing/stenosis
5. Signed consent for treatment

Exclusion criteria

1. Prior peritoneal CSF shunting, ONFS treatment, or endovascular procedure for IIH
2. No venous sinus pressure gradient or narrowing on DSA or venography
3. CT Venogram demonstrating dural AV fistula that may be causing venous hypertension
4. Venous sinus thrombosis causing venous hypertension
5. Severe allergic reaction or anaphylaxis to iodinated contrast / antiplatelets
6. Impaired renal function
7. Pregnancy

Chief Investigator

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We are seeking expressions of interest from Principal Investigators at potential recruiting centres throughout the UK.