

A prospective, randomised, controlled trial to evaluate the efficacy and safety of endoscopic choroid plexus coagulation with third ventriculostomy in the treatment of idiopathic Normal Pressure Hydrocephalus

Submission date 17/10/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/10/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/05/2016	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ian K Pople

Contact details
Department of Neurosurgery
Frenchay Hospital
Frenchay Park Road
Bristol
United Kingdom
BS16 1LE
+44 (0)117 975 3960
ikpople@hotmail.com

Additional identifiers

Study information

Scientific Title

A prospective, randomised, controlled trial to evaluate the efficacy and safety of endoscopic choroid plexus coagulation with third ventriculostomy in the treatment of idiopathic Normal Pressure Hydrocephalus

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Normal Pressure Hydrocephalus (NPH)

Interventions

Treatment group: Endoscopic third ventriculostomy and choroid plexus coagulation.
Control group: Programmable (Codman Medos valve) ventriculoperitoneal shunt.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2003

Eligibility

Key inclusion criteria

1. A clinical diagnosis of Normal Pressure Hydrocephalus (NPH) by the following criteria:
 - a. Evidence of significant gait disturbance in the absence of other causative factors
 - b. Evidence of some cognitive impairment on formal neuropsychological testing (Mattis

dementia rating scale and Folstein mini-mental state examination) and/or urinary incontinence or evidence of neurogenic urinary disturbance (frequency or urgency)
c. Lumbar Opening Pressure less than 20 mmHg on supine lumbar puncture
2. Symptom duration of more than six months
3. Evidence of disease progression since onset of symptoms
4. Radiological evidence of hydrocephalus, Evans ratio more than 0.3 on Computed Tomography (CT) scan of head
5. Patients must be fit enough to undergo operative surgical treatment, as defined by an American Society of Anesthesiologists (ASA) score of one, two or three
6. Written informed consent to participation in the study obtained from the patient, or next of kin if the patient is unable (due to cognitive impairment) to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2002

Date of final enrolment

01/10/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Neurosurgery

Bristol

United Kingdom

BS16 1LE

Sponsor information

Organisation

The Frenchay Hydrocephalus Research Fund (UK)

Funder(s)**Funder type**

Research organisation

Funder Name

The Frenchay Hydrocephalus Research Fund (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration