

# 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

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

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2002

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Not provided at time of registration

**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

England

United Kingdom

### Study participating centre

#### Department of Neurosurgery

Bristol

United Kingdom

BS16 1LE

## Sponsor information

### Organisation

The Frenchay Hydrocephalus Research Fund (UK)

### Sponsor details

Frenchay Hospital

Frenchay Park Road

Bristol

United Kingdom

BS16 1LE

### Sponsor type

Research organisation

### Website

<http://www.nbt.nhs.uk/>

## Funder(s)

### Funder type

Research organisation

### Funder Name

The Frenchay Hydrocephalus Research Fund (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration