

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
		<input type="checkbox"/> Protocol
Registration date 17/10/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/05/2016	Condition category 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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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