ISRCTN29863839 https://doi.org/10.1186/ISRCTN29863839

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

Registration date
17/10/2002

Overall study status
Completed

Last Edited
24/05/2016

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

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