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Shunt Valves plus shunt Assistant versus Shunt valves alone for controlling Overdrainage in idiopathic Normal-pressure hydrocephalus in Adults

Submission date
28/12/2006

Recruitment status
No longer recruiting

Registration date
18/05/2007

Overall study status
Completed

Last Edited
15/07/2013

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SVASONA Protocol Version 1.3 August 2006 (IRB approved)

Study information

Scientific Title

Acronym
SVASONA

Study objectives
Combined draining with a shunt valve and a shunt assistant decreases the rate of overdrainage (defined as a composite of clinical signs and symptoms, radiological findings, and therapeutic actions [i.e., pressure adjustment and/ or surgical revisions] taken to resolve the condition) from 25% to 10% comparing with a shunt valve alone six months after index surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was approved by the Institutional Review Board of the Charite University Medical Centre, Berlin (Germany) on 6th November 2006 (ref: EA1/165/06).

Study design
Open-label, pragmatic randomised controlled multicentre 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
Idiopathic Normal-Pressure Hydrocephalus (INPH) in adults

Interventions
Experimental arm: ProGAV P3 (PGV, Miethke, Germany) Adjustable/Gravitational Valve
Control arm: Medos-Codman Programmable Valve System (CHPV, Codman Johnson & Johnson, Germany)

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Composite measure of:
1. Clinical signs and symptoms suggestive of overdrainage (e.g., headache, vomiting, dizziness)
2. Imaging results (e.g., subdural haematoma, slit-ventricle syndrome)
3. Therapeutic interventions to resolve overdrainage

Secondary outcome measures
1. INPH outcome scales and Recovery Rate
2. 12-item Short-Form health survey (SF-12)
3. Evans-Index
4. Complication rates
5. Adverse Events (AE)
6. Serious Adverse Events (SAE)

Overall study start date
01/02/2007

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. Male and female subjects more than 18 years
2. High probability of Idiopathic Normal-Pressure Hydrocephalus (INPH), according to published guidelines and locally established protocols
3. The diagnosis will include clinical signs and symptoms (Hakim's triad), the findings from lumbal infusion and tap tests, intermittent drainage, and Computed Tomography (CT) results

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250 patients with adaptive O'Brien-Fleming design

Key exclusion criteria

1. Secondary Normal-Pressure Hydrocephalus (NPH) to inflammation
2. Tumour
3. Post-traumatic states
4. Contraindications for surgery (e.g., severe underlying diseases, florid infections)
5. Severe dementia

Date of first enrolment
01/02/2007

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Germany

Study participating centre
Department of Neurosurgery
Berlin
Germany
12683

Sponsor information

Organisation
B. Braun Melsungen AG (Germany)

Sponsor details
Carl-Braun-Strasse 1
Melsungen
Germany
34212
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Sponsor type
Industry

Website
http://www.bbraun.de/

ROR
https://ror.org/04nxj7050

Funder(s)

Funder type
Industry

Funder Name
Investigator-initiated and funded trial. Additional external funding for trial logistics and travel will be provided by Braun-Aesculap (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2010		Yes	No
Results article	results	01/08/2013		Yes	No