

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

|                                        |                                                      |                                                      |
|----------------------------------------|------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>28/12/2006   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>18/05/2007 | <b>Overall study status</b><br>Completed             | <input checked="" type="checkbox"/> Protocol         |
| <b>Last Edited</b><br>15/07/2013       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                      | <input checked="" type="checkbox"/> Results          |
|                                        |                                                      | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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).

### Primary study design

Interventional

### Study design

Open-label, pragmatic randomised controlled multicentre trial

### Study type(s)

Treatment

### 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(s)

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

### Key secondary outcome(s)

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)

**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 lumbar infusion and tap tests, intermittent drainage, and Computed Tomography (CT) results

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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)

### 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

### 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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 01/08/2013   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 01/04/2010   |            | Yes            | No              |