Plan Overview

A Data Management Plan created using DeiC DMP

Title: Ventriculo- vs lumbo-peritoneal shunt (VeLuP) treatment using gravitational valve technology for Normal Pressure Hydrocephalus treatment: study protocol for a randomised controlled trial

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Project abstract:

Background:
Idiopathic normal pressure hydrocephalus (iNPH) is a common yet underdiagnosed cause of dementia, characterized by gait disturbances, urinary incontinence, and cognitive decline. Surgical intervention with cerebrospinal fluid (CSF) diversion via shunt placement remains the only effective treatment. While ventriculo-peritoneal (VP) shunts are standard practice in Europe and North America, lumbo-peritoneal (LP) shunts — favored in Japan — offer potential advantages such as reduced invasiveness, shorter surgery time, and suitability for local anesthesia. However, robust comparative data on these approaches is lacking.

Objective:
The VeLuP trial is a Danish, single-center, randomized controlled, non-inferiority trial designed to compare the clinical effectiveness and safety of LP versus VP shunts using anti-gravitational valves in patients with iNPH. The primary hypothesis is that LP shunts are non-inferior to VP shunts in improving functional outcomes, as measured by the modified Rankin Scale (mRS), three months postoperatively.

Methods:
Eligible patients with suspected iNPH will undergo standard diagnostic evaluation, including imaging and, when appropriate, CSF tap testing. Following confirmation of surgical indication by a multidisciplinary team, patients will be randomized 1:1 to receive either an LP or VP shunt. The trial includes a pre-trial familiarization phase to ensure surgical proficiency. Primary outcome is improvement of at least one point on the mRS at three months. Secondary outcomes include improvements in the iNPH Grading Scale, duration of surgery, length of hospital stay, and complication rates. An interim analysis will be conducted after 50% recruitment, overseen by an independent statistician, with predefined stopping criteria for efficacy or safety concerns.

Perspectives:
If LP shunts demonstrate non-inferiority to VP shunts, this trial could support a shift toward less invasive surgical options, potentially reducing complications and improving patient outcomes, especially among the elderly and frail. The study fosters international collaboration, notably with centers of expertise in Japan, and contributes valuable data to guide clinical practice and future multicenter research.

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Data Collection

What data will you collect or create?

- Patient demographics (age, sex, BMI)
- Symptom profile (Hakim's Triad: gait disturbance, urinary incontinence, cognitive impairment)
- Imaging results (MRI, Evans Index)
- CSF tap test results
- Surgical details (shunt type, duration of surgery)
- Postoperative outcomes (complications, revisions, length of hospital stay)
- Standardized clinical scales: modified Rankin Scale (mRS), iNPH Grading Scale (iNPHGS)

How will the data be collected or created?

Clinical data will be collected prospectively during standard clinical visits prior to surgery and three months after surgery at the clinical follow-up.
Demographic data will be collected from the patients electronic journal.
Data will be entered directly into REDCap, a secure electronic case report form (eCRF) system

Documentation and Metadata

What documentation and metadata will accompany the data?

- Standard Operating Procedures (SOPs) for data collection and entry.
- Codebooks for variable definitions, scale scoring, and dataset structure.
- Audit trails in REDCap for data changes and user access logs.
- Metadata within REDCap describing data origins, formats, and collection dates

Ethics and Legal Compliance

How will you manage any ethical issues?

VeLuP will follow the Good Clinical Pratice (GCP) guidelines as well as the declaration of Helsinki. It will be approved by the Danish Health Research Ethics Committee
Informed consent will be obtained by a member of the research team after the iNPH diagnosis has been established and the indication for shunt treatment has been obtained. Danish law requires that patients are informed orally and in writing. The patients are made aware of their right to ample time and that informed consent can be withdrawn at any time. If they do not wish to take part in the trial, they will receive a VP shunt which currently is standard treatment in Denmark.
Patients who receive treatment in Denmark is covered by the Patient Compensation Association and can file a claim for an injury sustained because of the treatment. This also covers participation in clinical trials.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

- Data generated is owned by Odense University Hospital and the University of Southern Denmark, as per institutional policy.
- No commercial use of the data is planned; this is a non-commercial clinical study
- Anonomized data will be shared upon reasonable inquiry

Storage and Backup

How will the data be stored and backed up during the research?

All included patients are registered in REDCap, which is a worldwide online system developed specifically for non-commercial clinical research. REDCap is administered by the Open Patient data Explorative Network (OPEN) at Odense University Hospital, Odense, Denmark. The data entered will be stored on secure servers in the Region of Southern Denmark. Data is entered via an encrypted connection, are anonymized and meet the demands for data protection as per GDPR. All data entries are logged in REDCap and meets GCP requirements for use of Electronic Case Report Form (eCRF), when conducting medical trials

How will you manage access and security?

- Access is restricted to authorized research personnel with individual credentials.
- Data access is role-specific (e.g., data entry, monitoring, statistics).
- REDCap maintains detailed audit logs for all entries and modifications

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

- Anonymized clinical datasets (demographics, clinical outcomes, surgical details).
- Anonymized analysis datasets for primary and secondary outcomes.
- Metadata and documentation for reproducibility

These datagroups will be preserved should an external party wish to validate our results and statistics.

What is the long-term preservation plan for the dataset?

Data will be archived securely on OPEN's secure servers at Odense University Hospital for at least 10 years after study completion, in accordance with Danish regulations

Data Sharing

How will you share the data?

- Study results will be published in peer-reviewed, open-access journals.
- Data availability statements will be included in all publications. Anonomized data will be available on reasonable inquiry to the corresponding author.

Are any restrictions on data sharing required?

Only restriction is anonymization of the dataset. No data will be patented or otherwise restricted

Responsibilities and Resources

Who will be responsible for data management?

The principal investigator holds overall responsibility for data management. Data safety will be managed by REDCap.
An external third party statistician at OPEN will monitor the study and perform the interim analysis to make sure the study adheres to stopping criteria.

What resources will you require to deliver your plan?

The data collection will performed at the department in already existing work flows of patients. PI is trained in REDCap and a collaboration between the study team and OPEN has been established. All ressources and collaboration have been established so that the trial may begin as soon as funding has been achieved.