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Testing a drainage device for the treatment of hydrocephalus (a build-up of fluid in the brain)

Submission date
29/11/2022

Recruitment status
No longer recruiting

Registration date
30/11/2022

Overall study status
Completed

Last Edited
06/06/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
In a healthy individual, 400-500ml of brain fluid (also known as cerebrospinal fluid or CSF) is produced daily and passes around the brain before being re-absorbed into the bloodstream. Hydrocephalus (or “fluid on the brain”) is the condition where the flow of CSF becomes blocked, resulting in increased pressure within the brain cavity which can cause brain damage and eventually death if not treated.
There is no cure for the cause of hydrocephalus, but the condition is usually treated by having a shunt implanted which diverts the fluid from the ventricles of the brain to another part of the body (most often the stomach) where it re-enters the bloodstream. Hydrocephalus shunts save lives but the five-year survival rate for hydrocephalus shunts is only about fifty per cent. In fact, thirty per cent of patients are re-operated within three months due to shunt failure. This high failure rate is only accepted because there is no alternative treatment option. Since hydrocephalus patients are shunt dependent for life, patients, patient associations and surgeons are all desperate for better and more durable solutions.
CSF-Dynamics A/S has developed a new type of shunt, the SinuShunt®. The principle behind this shunt is that it mimics the normal physiological outflow of cerebrospinal fluid, directing the fluid into the vein in the head which is where CSF would normally drain. The design of the drain outlet (known as the VAP or Venous Access Port) is shaped like a stent. Stents are commonly used to keep blood vessels open, however in this case the stent is used to support the outlet in the centre of the vein. This part of the design is critical in preventing the outlet from drifting to the side of the vein where it could settle into the wall of the vein and become blocked.
The purpose of the study is to test the new outlet and ensure that it functions continuously for a period of 6 months.

Who can participate?
Only participants over the age of 18 who are suffering from hydrocephalus, need a hydrocephalus shunt and who fulfil all inclusion criteria will be admitted to the study.

What does the study involve?
Participants will be operated in the same way as standard hydrocephalus shunts with the

exception that the shunt outlet will be run to the jugular vein in the neck rather than the stomach. All patients will be operated in the same way and will be followed up at three and six months where the shunt system will be checked to ensure there is through-flow.

What are the possible benefits and risks of participating?
The benefit of participating in this study is that the device is designed to lengthen the average lifespan of the shunt system. The average lifespan of a standard shunt which diverts brain fluid to the stomach is 75% at six months. The VAP is designed to overcome issues of modern-day shunts and never need replacing.
There are two significant risks, the risk of blood clots and the risk of nerve irritation.
The VAP will be positioned on the right-hand side of the head. There is a possibility that locating the VAP in the middle of the vein may cause blood clots around the end of the outlet, and that this may block the flow of blood. To ensure that this risk does not become life-threatening if it happens, all patients will be checked to ensure they have continuous double outflow of blood, so that blood can still flow on the right side of the head should a blockage occur. In addition, to prevent any possible blood clot formation, the participant will be treated with 75mg of aspirin per day for the first 8 weeks after surgery. If a blood clot does form, the VAP will be removed and replaced by a standard shunt.
There is a also risk of nerve irritation because some nerves also pass through the hole in the base of the skull where the VAP will be positioned. These nerves are separated from the vein by a fibrous membrane which might be affected by the springy nature of the VAP, although this is unlikely due to the size and force of the device. This irritation has symptoms of spinning sensations behind the ear, dryness in the mouth and reduced sense of touch at the back of the tongue. These symptoms will be checked at the three and six month follow ups. If the discomfort is persistent, the VAP will be removed and replaced by a standard shunt.

Where is the study run from?
Odense University Hospital, Denmark

When is the study starting and how long is it expected to run for?
February 2019 to September 2022

Who is funding the study?
CSF-Dynamics A/S (Denmark)
European Innovation Council

Who is the main contact?
Dr Sune Munthe, sune.munthe@rsyd.dk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Test of Venous Access Port: feasibility study of a drainage device for the treatment of hydrocephalus

Study objectives
Shunt survival at 6 months will be 10% better than the average standard shunt lifespan at 6 months of 75%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2020, Ethics Committee of the Capital Region (Kongens Vænge 2, 3400 Hillerød, Denmark; +45 38 66 63 95; vek-anmeldelse.center-for-sundhed@regionh.dk), ref: H-19083791

Primary study design
Interventional

Study design
Single-arm single-centre prospective interventional feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hydrocephalus

Interventions
Implantation of Venous Access Port (VAP) as part of a shunt system for treatment of hydrocephalus.
Shunt comprises a cerebral ventricular catheter, a subcutaneous control-reservoir, a subcutaneous one-way valve, a subcutaneous silicone tube and a shunt-outlet placed intravascularly at the top of the internal jugular vein in the jugular foramen.
The shunt outlet is the investigational device and is also known as the Venous Access Port (VAP).

Shunt survival and function is tested by a water-column test through puncturing of control-reservoir and measuring pressure by height of water column and observing free inflow/no flow) at 3 months and 6 months.

Medication: antiplatelet treatment post-operatively with 75 mg aspirin per day for 8 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Venous Access Port (VAP)

Primary outcome(s)
VAP remains open at the 3 month and 6 month endpoint tested by water column test

Key secondary outcome(s)
1. Registration of clinical symptoms at inclusion and at 3 and 6 month follow-up measured using:
1.1. gait disturbances, evaluated by investigator in three levels (normal gait, moderate disturbance, severe disturbance)
1.2. dementia degree, evaluated by investigator in three levels (no dementia, moderate dementia, severe dementia)
1.3. incontinence evaluated by investigator in three levels (no incontinence, moderate incontinence, severe incontinence)
2. Overdrainage measured using MRI scan at 3 and 6 month follow up: observation of subdural haematoma or CSF effusion. Measurement of Evans' ratio.

Completion date
20/09/2022

Eligibility

Key inclusion criteria
1. Neuroradiologically verified enlarged ventricular system
2. Either one or more of the following symptoms of hydrocephalus requiring treatment: headache, nausea, visual disturbances, cognitive dysfunction, difficulty walking, urinary incontinence, or have a previously implanted shunt that requires revision
3. Reserve drainage (cross-flow) to opposite sinuses transversus, demonstrated by MRI venogram
4. Jugular foramen with minimum diameter >7 mm on MRI scan
5. Normal lung scintigraphy with no evidence of sequelae from previous blood clots in the lungs
6. Normal coagulation status
7. May be treated by one of the surgeons associated with the study.
8. Is 18 years of age or older
9. Provision of signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Pregnant (test: urine stick HCG test, laboratory test code NPU10394)
2. Normal size ventricular system
3. Suspected of having multiple infarctus or leukodystrophic changes that may cause enlarged ventricular system
4. Paraclinical signs of affected coagulation function
5. Known allergy to nickel, Zinacef™ or acetylsalicylic acid

Date of first enrolment
22/06/2020

Date of final enrolment
25/02/2022

Locations

Countries of recruitment
Denmark

Study participating centre
Odense University Hospital
Neurokirurgisk Afdeling U
Sdr. Boulevard 29
Odense C
Denmark
5000

Sponsor information

Organisation

CSF-Dynamics A/S

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/04/2023	06/06/2023	Yes	No