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Programmable versus fixed anti-siphon devices for normal pressure hydrocephalus

Submission date
13/10/2016

Recruitment status
No longer recruiting

Registration date
10/11/2016

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Idiopathic normal pressure hydrocephalus (iNPH) is a distinct form of dementia, characterized by gait ataxia (uncoordinated movements), cognitive impairment (memory and thinking problems) and urinary incontinence. Unlike all other causes of dementia (e.g. Alzheimer type, and others), a type of surgery called ventriculo-peritoneal (VP) shunt surgery may actually cure patients. This surgery involves a medical device (shunt) being implanted to relieve pressure on the brain caused by the build up of fluid. While being a rather low-risk type of surgery, it may cause significant over- or under-drainage complications when changing position, such as headaches, dizziness, vomiting and bleeding in the brain. Fixed Anti-siphon devices (ASD) are an optional part of the draining systems used for shunt surgery and have been proven to decrease the rate of overdrainage complications effectively. Nevertheless, no significant differences could be found concerning the ability to avoid under-drainage complications. Technical successor of fixed ASDs are programmable ASDs. The aim of this study is to evaluate whether programmable ASDs compared to fixed ASDs are able to avoid both over and under-drainage complications at all.

Who can participate?
Adults with iNPH who are going to have VP shunt surgery and are able to consent to take part.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have a shunt with a programmable ASD implanted. Those in the second group have a shunt with a fixed ASD implanted. Surgery for participants in both groups takes between 45 and 90 minutes. At the start of study and then again after three, six and twelve months participants in both groups are examined by a doctor to assess underdrainage and overdrianage rates. In addition, participants complete questionnaires and have a CT scan (a special type of x-ray) to look for any complications.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. Both fixed and programmable ASDs are approved in the European Union (EU) and used in daily practice and so taking part in unlikely to involve any risks other than the typical risks associated with undergoing major surgery.

Where is the study run from?
Unfallkrankenhaus Berlin (Germany)

When is the study starting and how long is it expected to run for?
January 2016 to December 2020

Who is funding the study?
Aesculap AG (Germany)

Who is the main contact?
Professor Ullrich Meier
Ullrich.Meier@ukb.de

Contact information

Type(s)
Scientific

Contact name
Prof Ullrich Meier

Contact details
Department of Neurosurgery
Unfallkrankenhaus Berlin
Warener Str. 7
Berlin
Germany
12683

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sygrava V 5.02

Study information

Scientific Title
Multicentre randomized trial evaluating the efficacy and safety of programmable compared with fixed anti-siphon devices for idiopathic normal pressure hydrocephalus (iNPH) in adults

Acronym
SYGRAVA

Study objectives

In patients undergoing ventriculoperitoneal (VP) shunt surgery for iNPH, the use of programmable valves with programmable ASD lowers the composite incidence of under- and over-drainage complications from 27% to 10% six months after randomization compared to the standard of care (i.e., programmable valves with fixed ASD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Charité University Medical Centre, 02/09/2016, ref.: EA1/234 /16

Study design
Pragmatic multi-centre open-label randomized controlled 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)

Interventions
Participants are randomised to one of two groups immediately before surgery using the web-based randomization and documentation platform (SecuTrialTM). A block randomization scheme with a block length of four and an allocation ratio of 1 : 1 will be employed.

Intervention group: Participants will undergo ventriculoperitoneal shunt surgery with a combination of a programmable valve with programmable ASD device (Miethke proGAV® with proSA®). The proSA® increases the valve opening pressure in the upright position by a programmable additional gravitational valve mechanism.

Control group: Participants will receive a ventriculoperitoneal shunt with a programmable valve plus fixed ASD device to prevent overdrainage by a non-adaptive mechanism which increases the opening pressure in the upright position by narrowing of the inner diameter of the valve outlet (Medtronic PS Medical Strata II® valve with Delta Chamber® or Codman Certas plus® with SiphonGuard® depending on the preference or availability at individual centres).

Surgery will take between 45 and 90 minutes. Patients will be followed up three, six and twelve months after surgery. All follow-up visits will comprise:
1. History taking and physical examination

2. Computed tomography (CT) imaging of the head
3. Recording of clinical, physical, and / or radiographic signs of over- or underdrainage
4. Health-related quality of life assessment, using the SF-12 and EQ-5D questionnaires
5. Specific outcome measures (e.g., Kiefer Score, Black Grading Scale, 10 min walk / 360° test)
6. Pressure adjustment of one or both valve components according to individual requirements
7. Documentation of any adverse event

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Cumulative incidence of over- or underdrainage is measured through clinical observations 6 months post-surgery.

Secondary outcome measures
1. Individual rates of overdrainage measured by clinical evaluation at 3, 6 and 12 months
2. Individual rates of underdrainage measured by clinical evaluation at 3, 6 and 12 months
3. Slit ventricle syndrome as detected by CT imaging at 3, 6 and 12 months
4. Subdural effusions as detected by CT imaging at 3, 6 and 12 months
5. Infections measured by clinical evaluation at 3, 6 and 12 months
6. Neurofunctional outcomes measured by Kiefer Score, Black Grading Scale, 10 min walk test and 360° test at baseline, 3, 6 and 12 months
7. Health-related quality of life measured by SF-12 and EQ-5D at baseline, 3, 6 and 12 months

Overall study start date
10/01/2016

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Meet clinical, physiological, functional and radiological diagnostic criteria of iNPH
2. Scheduled for VP shunting
4. Capable to understand the trial concept and its implications, and to provide written (or witnessed verbal) informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
306

Key exclusion criteria
1. Secondary NPH after infection, trauma, tumours, etc.
2. Contraindication for shunt surgery (e.g., malignant disease with reduced life expectancy, florid infections etc.)
3. Advanced dementia
4. Guardianship
5. Any impediment prohibiting informed consent
6. Patients with previous shunt implantation
7. Patients with previous ventriculostomy

Date of first enrolment
01/12/2016

Date of final enrolment
04/12/2019

Locations

Countries of recruitment
Germany

Study participating centre
Unfallkrankenhaus Berlin
Department of Neurosurgery
Warener Str. 7
Berlin
Germany
12683

Study participating centre
University Medical Centre Göttingen
Department of Neurosurgery
Göttingen
Germany
37075

Study participating centre
Dietrich-Bonhoeffer-Hospital Neubrandenburg
Department of Neurosurgery
Neubrandenburg
Germany
17022

Study participating centre
Heidelberg University Hospital
Department of Neurosurgery
Heidelberg
Germany
69120

Study participating centre
Saarland University Medical Center
Department of Neurosurgery
Homburg/Saar
Germany
66421

Study participating centre
University Medicine Greifswald
Department of Neurosurgery
Greifswald
Germany
17475

Sponsor information

Organisation
Unfallkrankenhaus Berlin

Sponsor details
Department of Neurosurgery
Warener Str. 7
Berlin
Germany
12683

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/011zjcv36

Funder(s)

Funder type
Industry

Funder Name
Aesculap AG

Results and Publications

Publication and dissemination plan
The primary and secondary results of this trial will be published in an open-access fashion in peer-reviewed periodicals, preferably in general medical journals. This will be accompanied by presentation of findings at international conferences.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/10/2018		Yes	No