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The British Antibiotic and Silver Impregnated Catheters for ventriculoperitoneal Shunts multi-centre randomised control trial

Submission date
11/12/2012

Recruitment status
No longer recruiting

Registration date
17/12/2012

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Two new devices have been introduced to try to reduce shunt infection; Bactiseal and Silverline shunts. This study will compare these new shunts to standard shunts. Our goal is to establish which provides most protection against infection and to ensure standardisation of care.

Who can participate?
Children and adults with newly diagnosed hydrocephalus.

What does the study involve?
Patients will be randomly chosen to receive either standard, Bactiseal or Silverline shunts. The patient will have a follow up every three months via the telephone and a questionnaire by post.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future patients requiring this treatment as they will potentially have reduced shunt infection. The main risk of infection is complications for the patients which can leads to prolonged hospital stay, multiple operations and reduced IQ.

Where is the study run from?
Alder Hey Childrens Hospital NHS Foundation Trust.

When is study starting and how long is it expected to run for?
Recruitment will start in early 2013, for 2 years. Patients will be followed up for a maximum of 2.5 years.

Who is funding the study?
National Institute of Health Research Health Technology Assessment Programme

Who is the main contact?
Mr Tom Kearns
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Study website
http://www.basicsstudy.org.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.0; HTA 10/104/30

Study information

Scientific Title
National three-arm, double blind multi-centre randomised controlled trial comparing Bactiseal (antibiotic-impregnated), Silverline (silver-impregnated) and standard (non-impregnated) VPS in patients with newly diagnosed hydrocephalus undergoing insertion of their first permanent shunt

Acronym
BASICS

Study objectives
Shunt failure due to infection has plagued this neurosurgical advance ever since it was developed. The incidence of shunt infection varies markedly in the literature from 3-27% (2-6) and is higher in certain groups, e.g. neonates and children under 1 year old, patients treated with a previous temporary external ventricular drain (EVD). Episodes of shunt infection have a

significant impact on patients and the NHS and require prolonged inpatient hospitalisation, additional surgery to remove the infected hardware, placement of a temporary EVD, intravenous and intrathecal antibiotics, and further surgery to place a new shunt once the infection has been treated. Other clinical consequences of infection including epilepsy, reduced IQ and loculation have often been reported but never formally studied in the context of a prospective clinical trial. This trial thus addresses the primary question of which shunt catheter is most effective in reducing shunt infection and also has secondary questions addressing the consequences of infection in a clinical and financial context.

More details can be found here: http://www.hta.ac.uk/project/2902.asp

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Three-arm multi-centre phase III randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Newly diagnosed hydrocephalus

Interventions
We will randomly allocate patients to a standard non impregnated ventriculoperitoneal shunt (VPS), a
Silverline (Silver impregnated) VPS or a Bactiseal (antiobiotic impregnated) VPS on a ratio of 1:1:1. All VPS
used for the trial are CE marked medical devices being used for their intended purpose.

Intervention Type
Device

Phase
Phase III

Primary outcome measure
Early infection (within 6 months) following insertion of the first de novo VPS

Secondary outcome measures
1. The proportion of delayed VPS infections (occurring > 6 months following de novo insertion)
2. Which organisms and their resistance/sensitivities, subsequently infect these three alternative VPS
3. The clinical impact of each VPS infection
4. The infection rate following the first (non-infected) clean VPS revision for mechanical failure
5. The cost-effectiveness and health economics of antibiotic and silver impregnated VPS compared to standard VPS
6. The diagnostics of suspected shunt infections through molecular diagnostic approaches

Overall study start date
01/03/2013

Completion date
01/08/2013

Eligibility

Key inclusion criteria
1. Newly diagnosed hydrocephalus of any aetiology (including idiopathic intracranial hypertension)
2. VPS is the primary treatment option
3. Clear CSF sample at the time of shunt insertion
3.1. Failed primary endosopic third ventriculostomy allowed
3.2. Previous indwelling ventricular access device (e.g. Ommaya or Rickham reservoir or similar) allowed
3.3. Previous indwelling EVD allowed

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Total final enrolment
1605

Key exclusion criteria
1. Previous indwelling VPS
2. Active and on-going CSF or peritoneal infection

3. Multi-loculated hydrocephalus requiring multiple VPS or neuro-endoscopy
4. Ventriculo-atrial or ventriculo-pleural shunt planned
5. Allergy to antibiotics associated with the antibiotic shunt

Date of first enrolment
01/03/2013

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
England

Ireland

United Kingdom

Study participating centre
Alder Hey Childrens NHS Foundation Trust
Liverpool
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Sponsor information

Organisation
Alder Hey Children's Hospital Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme: 10/104/30

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	03/01/2014		Yes	No
Results article	results	26/10/2019	17/09/2019	Yes	No
Results article	results	01/03/2020	03/04/2020	Yes	No
Results article	Post hoc analysis	01/02/2023	06/02/2023	Yes	No