

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	☒ Prospectively registered ☒ Protocol
Registration date 17/12/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/02/2023	Condition category Nervous System Diseases	☐ 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 lead 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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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 (antibiotic 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(s)

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

Key secondary outcome(s))

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

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 endoscopic 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Ireland

Study participating centre

Alder Hey Childrens NHS Foundation Trust
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation

Alder Hey Children's Hospital Foundation Trust (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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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
Protocol article	protocol	03/01/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes