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Silver Impregnated Line Versus External Ventricular Drains (EVD) Randomised Trial

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 19/09/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Cambridge LREC 04/Q0108/247

Study information

Scientific Title
Silver Impregnated Line Versus EVD Randomised Trial and Cerebrospinal Fluid Infection from the use of External Ventricular Drains

Acronym
SILVER Trial

Study objectives
Silver impregnated lines (external ventricular drains with silver lining) cause fewer cerebrospinal fluid (CSF) infections than plain standard EVD catheters.

Please note that as of 19/04/10 this trial has been extensively updated. All updates may be found in the relevant field with the above update date. Please also note that the anticipated start and end dates of the trial 01/07/05 to 31/07/07 have been changed to the actual start and end dates 01/06/05 to 31/09/09. A second site, Southampton, also joined the trial after the last recorded update (03/12/07)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 19/04/10
1. Cambridge Local Research Ethics Committee approved in February 2005 (ref: 04/Q0108/247)
2. Southampton Local Research Ethics Committee approved in November 2006

Study design
Double blind randomised plain controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Information sheets and consent forms as approved by local ethics committees

Health condition(s) or problem(s) studied
Cerebrospinal fluid infection, external ventricular drains for raised intracranial pressure, ventriculomegaly or hydrocephalus

Interventions

Current information as of 19/04/10:
Participants were randomised to receive either a silver impregnated EVD or a plain standard EVD for the duration of their EVD requirement to treat raised intracranial pressure, hydrocephalus or ventriculomegaly.

Initial information at time of registration:
Silver impregnated lines (external ventricular drains with silver lining) versus plain standard EVDs.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current information as of 19/04/10:
CSF infection as defined by organisms seen on gram stain or grown on culture during the EVD period

Initial information at time of registration
CSF infection confirmed by culture of organisms

Secondary outcome measures
Current information as of 19/04/10:
1. Number of EVD replacements
2. Duration of EVD placement
3. Antibiotic treatment required for CSF infection (confirmed or suspected)
4. Total time from admission to discharge
5. Permanent ventriculoperitoneal (VP) shunt required at 6 months
6. Clinical outcome at discharge (Glasgow Coma Score)

Initial information at time of registration:
1. Number of EVD replacements
2. Duration of EVD placement
3. Antibiotic treatment required for CSF infection (confirmed or suspected)
4. Total time from admission to discharge
5. Permanent ventriculoperitoneal (VP) shunt required
6. Clinical outcome at discharge (Glasgow Coma Score)

Overall study start date
01/06/2005

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Current information as of 19/04/10:
All patients 17 years and over requiring an EVD for management of their intracranial pathology

referred to Cambridge University Hospitals NHS Foundation Trust, Cambridge and Wessex Neurological Centre, Southampton

Initial information at time of registration:
All patients requiring an EVD for management of their intracranial pathology referred to Cambridge University Hospitals NHS Foundation Trust

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140 in each arm (2 arms) - total 280

Key exclusion criteria
1. Patients with a known allergy to silver
2. Patients who are pregnant
3. The presence of infection or dermatitis at the catheter insertion site
4. Known cerebrospinal fluid (CSF) infection (gram-stain or culture of organisms)
5. A previous EVD placement within the previous 30 days
6. Refractory coagulopathy
7. Currently the trial is only open to patients who are 17 years or above

Date of first enrolment
01/06/2005

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box 166, Department of Neurosurgery
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Box 166, Department of Neurosurgery
Cambridge University Hospitals NHS Foundation Trust
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
Current information as of 19/04/10:

Funder Name
The trial has been run as a clinical investigation involving two neurosurgical units - Cambridge University Hospitals NHS Foundation Trust and Wessex Neurological Centre, Southampton. The trial EVDs were cost-neutral to both trusts as compared to non-study catheters. There was no cost benefit to either the units or the investigators

Funder Name
Initial information at time of registration:

Funder Name

The trial is run as a clinical investigation by Cambridge University Hospitals NHS Foundation Trust . The trial EVDs are purchased at the same price as the EVDs currently in clinical use. There is no cost benefit to the investigators.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2012		Yes	No