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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Miss Nicole Keong

#### Contact details

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# Additional identifiers

#### Protocol serial number

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

#### **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

# Study type(s)

Treatment

# 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(s)

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

#### Key secondary outcome(s))

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)

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

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

United Kingdom CB2 2QQ

# Sponsor information

# Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

#### **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**

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes