

# Prospective, randomised, double-blind trial of heparin or 0.45% saline infusion through the long line to reduce the incidence of long line sepsis in very low birth-weight infants

<b>Submission date</b> 08/05/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/05/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/04/2016	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

06/Q0403/14

## **Study information**

### **Scientific Title**

Prospective, randomised, double-blind trial of heparin or 0.45% saline infusion through the long line to reduce the incidence of long line sepsis in very low birth-weight infants

### **Acronym**

HILL study

### **Study objectives**

Intravenous heparin infusion reduces bacterial adherence in long lines by reducing fibronectin deposition and thereby reducing the incidence of long line sepsis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

St Mary's Local Research Committee, 11/05/2006, ref: 06/Q0403/14

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Long line infections in very low birth-weight (VLBW) infants

### **Interventions**

The trial has started enrolling patients from 1st September 2007.

Heparin infusion in long line versus placebo (0.45% saline infusion).

### **Intervention Type**

Drug

**Phase**

Not Specified

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

Heparin

**Primary outcome measure**

1. Reduction in the rate of long line infections
2. Increase in the longevity of long lines
3. Reduction in the number of long lines used
4. To record any adverse effects e.g. bleeding tendencies associated with the use of heparin

**Secondary outcome measures**

1. Reduction in catheter-related thromboses

**Overall study start date**

01/08/2006

**Completion date**

31/07/2009

## **Eligibility**

**Key inclusion criteria**

Infants admitted to Winnicott Baby Unit (Neonatal Intensive Care Unit [NICU]), St Mary's Hospital and born with birth weight <1500 g and who need a long line inserted for any medical indication and for whom written parental consent has been obtained are eligible to enter the study. Each baby can be enrolled only once in the study - the same infant will not be enrolled for the study again if he/she needs another long line inserted and if he/she has already been in the study before.

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

128 very low birth-weight (VLBW) infants

**Key exclusion criteria**

1. Infants who have a persisting haemorrhagic diathesis at time of proposed insertion of long line (LL). (International normalised ratio [INR] >1.8, activated partial thromboplastin time [APTT] >79.4 sec: Andrew M, et al 1988. Blood 72:1651-7)
2. Infants for whom parents have refused consent

3. Infants with birth weight  $\geq 1500$  g
4. Infants who have a  $\geq$  grade 3 intraventricular haemorrhage, unilaterally or bilaterally (by Papille's classification)
5. Infants with culture proven infection within 48 hours prior to long line insertion
6. Infants with platelet counts  $< 100 \times 10^9/l$
7. Infants who are deemed clinically unstable by the attending clinician but not from getting a LL

**Date of first enrolment**

01/08/2006

**Date of final enrolment**

31/07/2009

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

St Mary's Hospital, Bays Building

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## Sponsor information

**Organisation**

St Mary's Hospital (UK)

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**Sponsor type**

Government

**ROR**

<https://ror.org/001x4vz59>

# Funder(s)

## Funder type

Government

## Funder Name

St Mary's Hospital NHS Trust (UK)

# 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