

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

Submission date 08/05/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/05/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 27/04/2016	Condition category Neonatal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

1. Reduction in catheter-related thromboses

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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 ≥ 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**

United Kingdom

England

Study participating centre
St Mary's Hospital, Bays Building
London
United Kingdom
W2 1NY

Sponsor information

Organisation
St Mary's Hospital (UK)

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

Funder(s)

Funder type
Government

Funder Name
St Mary's Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration