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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

Registration date
26/05/2006

Overall study status
Completed

Last Edited
27/04/2016

Condition category
Neonatal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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, activited 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 ≥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 x 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
London
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W2 1NY

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