ISRCTN32517537 https://doi.org/10.1186/ISRCTN32517537

The effect of heparin on parenteral lipid metabolism and tolerance in newborns

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 07/11/2014	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Robert J McClure

Contact details
Box No 226
Neonatal Unit
The Rosie Hospital
Cambridge
United Kingdom
CB2 2SW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544093489

Study information

Scientific Title

Study objectives
The effects of heparin on intravenous nutrition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases: Lipid metabolism

Interventions
1. Parenteral nutrition with heparin
2. Parenteral nutrition without heparin

Heparin is commonly added to the infusions of neonatal patients, to prevent line blockage. This study is to determine whether the addition of heparin to parenteral nutrition (PN) infusions both allows lipid intake to be safely increased and central line complications to be reduced in ill newborn infants requiring PN. The hypothesis is that heparin added to a PN regimen using 20% Intralipid will allow increased lipid, calorie intake and reduced central line complications without increasing serum free fatty acids (FFA), thyroglobulin (TG) or cholesterol to unacceptable levels. Infants that require PN will be randomised in pharmacy (on receipt of first PN order) to receive PN either with or without heparin added at a dosage of 1 unit/ml Vamin-J amino acid solution. PN will be prescribed as usual according to unit policy. Attending medical and nursing staff on the neonatal unit will be blind to whether PN contains heparin.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2000

Completion date
31/08/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
140 subjects

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2000

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Box No 226
Cambridge
United Kingdom
CB2 2SW

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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