

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/11/2014	<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

**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