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A study of serially measured cystatin C and iohexol clearance for the determination of glomerular filtration rate (GFR) in pre-term neonates

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/11/2014	**Condition category** Pregnancy and Childbirth	

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
N0112112982

Study information

Scientific Title

Study objectives
1. To determine whether serum cystatin C provides a more accurate estimate of glomerular filtration rate (GFR) than creatinine in a pre-term neonatal population
2. To determine whether serum cystatin C levels differ significantly between asphyxiated and representative non-asphyxiated neonates

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)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Renal injury in preterm neonates

Interventions
Measures to be taken for glomerular filtration rate:
1. Serum cystatin C
2. Creatinine

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Validated test for renal injury in neonates

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/12/2001

Completion date
07/12/2003

Eligibility

Key inclusion criteria
Pre-term infants from the Neonatal Unit at St Helier Hospital, less than 37 weeks gestation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
07/12/2001

Date of final enrolment
07/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Epsom and St Helier NHS Trust
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals 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