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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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
05/11/2014

Condition category
Pregnancy and Childbirth

[ ] 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

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
Validated test for renal injury in neonates

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Epsom and St Helier University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration