

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
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 05/11/2014	Condition category Pregnancy and Childbirth	☐ 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

Contact name

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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