

The effects of aluminium exposure in the neonatal period on brain, cognition and bone health in children born preterm

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/04/2011	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0012146854

Study information

Scientific Title

Study objectives

This study sets out to investigate whether aluminium toxicity due to contaminate of intravenous feeding solutions cause long lasting adverse effects on brain, cognition and bone health.

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)

Not Specified

Health condition(s) or problem(s) studied

Neonatal Diseases: feeding

Interventions

1. Standard feeding solution
2. Specially constituted feeding solution

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

Children born prematurely and require intravenous feeding

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

c/o Research & Development Office

London

United Kingdom

WC1N 3JH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Great Ormond Street Hospital for Children NHS Trust / Institute of Child Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No