ISRCTN58031154 https://doi.org/10.1186/ISRCTN58031154

Randomised controlled trial of acetate in preterm neonates receiving parenteral nutrition

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/11/2010	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal diseases

Interventions
Standard parenteral nutrition vs novel formulation with replacement of any chloride dose >3 mmol/kg/day as acetate

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1995

Completion date
30/07/1996

Eligibility

Key inclusion criteria
Preterm neonates under 32 weeks gestation were entered into the study if they were still receiving intravenous glucose/electrolyte solution on day 3, but not receiving enteral nutrition.

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
Added as of 23/05/2008: 30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/1995

Date of final enrolment
30/07/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Neonatal Unit
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/1997		Yes	No