ISRCTN22535466 https://doi.org/10.1186/ISRCTN22535466

Effect of Continuous Intra Arterial Weak Bicarbonate Infusion on the Use of Fluid and Bicarbonate Boluses to Correct Metabolic Acidosis in Babies Weighing Less than 1000 g and Who are Less than 32 Weeks Gestation at Birth

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 15/05/2012	**Condition category** Neonatal Diseases	

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
N0051113384

Study information

Scientific Title

Study objectives
A continuous infusion of bicarbonate in very low birth weight infants over the first four days of life will reduce the need for bolus bicarbonate or fluid infusions to correct academia.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases: Metabolic acidosis

Interventions
Randomised controlled trial

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Continuous weak alkali infusion may prevent acidosis from occurring and reduce the need for boluses of fluid or bicarbonate.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/10/2001

Completion date
30/08/2004

Eligibility

Key inclusion criteria
Babies 32 weeks gestational age weighing <1000 g

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/10/2001

Date of final enrolment
30/08/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RSCH)
Brighton
United Kingdom
BN2 5BE

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
Hospital/treatment centre

Funder Name
Brighton and Sussex 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/04/2005		Yes	No