

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/05/2012	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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