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Randomised Asphyxia Study (RAST) - pilot phase. A multi-centre controlled study of magnesium infusion following severe birth asphyxia

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/01/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2019	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

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
G9436455

Study information

Scientific Title
Randomised Asphyxia Study (RAST) - pilot phase. A multi-centre controlled study of magnesium infusion following severe birth asphyxia

Acronym
RAST

Study objectives
Birth asphyxia remains one of the most important causes of potentially avoidable death and disability in normally formed fullterm babies in Britain. One of the most important causes of neuronal compromise following hypoxic-ischaemic insult is excessive calcium entry through the specific glutamate ligand port referred to as the N-methyl-D-aspartate (NMDA) channel. Magnesium ions block depolarization of the NMDA channel and MgSO4 has been widely used in pregnancy to prevent premature labour and to treat severe pregnancy induced hypertension. In these dosage regimens it appears to be safe to the neonate.
This pilot study proposes to evaluate the feasibility of using MgSO4 as a potential rescue therapy given shortly after resuscitation in infants who are severely depressed 10 minutes after birth. The pilot study will address:
1. The earliest postnatal age at which MgSO4 can be given with informed parental consent
2. Safety and pharmacokinetics of MgSO4 (250 mg/kg)
3. Feasibility of recruiting sufficient babies to have suitable statistical power to show an effect
4. Appropriate end point measures
The proposed pilot study will last 18 months and we aim to enroll at least 75 babies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Neonatal diseases: Neonatal diseases; Respiratory tract diseases: Other respiratory tract disease

Interventions
Not provided at time of registration

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
09/01/1995

Completion date
31/03/1997

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
75 babies

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
09/01/1995

Date of final enrolment
31/03/1997

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS2 9NS

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 Northern and Yorkshire (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