

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/10/2019	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 MgSO<sub>4</sub> 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 MgSO<sub>4</sub> 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 MgSO<sub>4</sub> can be given with informed parental consent
2. Safety and pharmacokinetics of MgSO<sub>4</sub> (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