# Nasal intubation influences weaning onto full oral feeds in neonates

Submission date	Recruitment status	Prospectively registered
29/09/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	Results
Last Edited	Condition category	[] Individual participant data
22/09/2014	Neonatal Diseases	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Miss Rachelle Mayo

### Contact details

Brighton & Sussex University Hospitals NHS Trust (RA) Royal Alexandra Childrens Hospital Dyke Road Brighton United Kingdom BN1 3JN +44 01273 328156 ext 2143

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0051166168

# Study information

### Scientific Title

# **Study objectives**

Does nasal intubation give the potential for quicker weaning onto full oral feeds by allowing earlier introduction of odometer exercises, non-nutritive sucking and positive oral experiences?

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Not provided at time of registration

# Study design

Randomised controlled trial with parallel group comparison - pilot study

# Primary study design

Interventional

### Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Other

### Participant information sheet

# Health condition(s) or problem(s) studied

Neonatal diseases

#### **Interventions**

This will be a randomised controlled trial with parallel group comparison. Babies will be allocated to either a nasal or an oral intubation group (via a sealed envelope). It is planned that those babies requiring ventilatory support will be intubated at birth by whatever method is considered the safest and most convenient at the time. Intubation tubes are routinely changed during the first week of life, and it is at this stage that the baby will be randomly allocated into either the oral or the nasal intubation group (if parental consent has been given).

### Intervention Type

Other

#### **Phase**

Not Applicable

# Primary outcome measure

- 1. Comparison of weaning onto full oral feeding in nasally intubated vs orally intubated babies
- 2. Time taken until first oral feed attempted, time taken until first oral feed completed
- 3. Time taken until 85% feeds are taken orally
- 4. Length of inpatient stay
- 5. Weight gain
- 6. Number of failed procedures, number of tube changes and the reason for change

# Secondary outcome measures

Not provided at time of registration

### Overall study start date

01/06/2005

# Completion date

01/03/2006

# Eligibility

### Key inclusion criteria

Babies will be eligible for the research if they are: born between 25 and 40+6 weeks gestation, booked within the NHS trust, or transferred to the trust ex utero within the first seven days of life and require ventilatory support.

### Participant type(s)

Patient

### Age group

Neonate

#### Sex

**Not Specified** 

# Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Babies will be excluded if they have significant congenital abnormalities, require surgical intervention, have significant neurological anomalies (i.e., Grade III IVH or higher, or any evidence of fitting), or if they only require mechanical ventilation for 24 hours or less.

### Date of first enrolment

01/06/2005

### Date of final enrolment

01/03/2006

# Locations

### Countries of recruitment

England

# **United Kingdom**

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RA)
Brighton
United Kingdom
BN1 3JN

# Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

### 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.dh.gov.uk/Home/fs/en

# Funder(s)

### Funder type

Government

### **Funder Name**

Brighton and Sussex University Hospitals NHS Trust (UK)

### **Funder Name**

NHS R&D Support Funding

# **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