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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	[ ] 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
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
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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