

Nasal intubation influences weaning onto full oral feeds in neonates

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/09/2014	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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial with parallel group comparison - pilot study

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

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**

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration