

The effect of positioning on the transition from tube to oral feeding in preterm infants: A pilot study

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 05/10/2011	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

Contact name

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Additional identifiers

Protocol serial number

N0436165577

Study information

Scientific Title

Study objectives

This pilot study aims to look at two small groups of preterm infants as they progress from nasogastric tube feeds to oral feeds and determine whether positioning the infants in side-lying enables a smoother transition to occur.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Neonatal Diseases

Interventions

Positioning technique 1 vs positioning technique 2

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary outcome measure is the time taken (in days) to attain full oral feeding. This is defined as the number of days necessary to make the transition from full nasogastric feeding to full oral feeding.

Key secondary outcome(s)

Secondary outcomes include a measure of oxygen desaturation events and a measure of the time (in days) taken until supplemental oxygen is no longer required (for those infants needing supplemental oxygen at the start of the study).

Completion date

27/03/2006

Eligibility

Key inclusion criteria

The pilot study will examine preterm infants (infants born with a gestational age of 36 completed weeks or less).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

Key exclusion criteria

Infants will be excluded if they are medically unstable, have either a cleft lip or palate, have identified neurological symptoms, have congenital anomalies, have known maternal substance abuse, will be discharged to other neonatal units before full oral feeding is established have a gestational age of 37 weeks or above or who are breastfed.

Date of first enrolment

01/03/2005

Date of final enrolment

27/03/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Speech and Language Therapy

Leeds

United Kingdom

LS8 3LG

Sponsor information**Organisation**

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

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration