ISRCTN37521560 https://doi.org/10.1186/ISRCTN37521560

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
Mrs Kate Jones

Contact details
Speech and Language Therapy
Child Development Centre
3rd Floor, Oaktree House
408 Oakwood Lane
Leeds
United Kingdom
LS8 3LG
+44
Kate.jones018@virgin.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure

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.

Secondary outcome measures
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).

Overall study start date
01/03/2005

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

Age group
Neonate

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

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
Leeds Teaching Hospitals NHS Trust (UK), 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