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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 02/10/2017	**Condition category** Neonatal Diseases	

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

N0626168625

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot RCT

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
Positioning on the transition from tube to oral feeding in preterm infants

Interventions
This pilot study will take place on a local neonatal unit and will examine the bottle feeding skills of premature infants whilst they are being fed either an elevated side-lying position, or a traditional semi-upright position. Infants will be studied from the time that oral feeds are first introduced until the infant is taking all bottle feeds and the nasogastric tube is no longer required.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2005

Completion date
31/05/2006

Eligibility

Key inclusion criteria
At the time of first introduction to oral feeds, preterm infants (infants born with a gestational age of 36 completed weeks or less) will be randomly allocated to either the intervention or the control group. Randomisation will be my means of sealed envelopes containing either the words elevated side-lying position or traditional position. The aim is to have five participants in each group.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Infants will be excluded if they are medically unstable
2. Have either a cleft lip or palate
3. Have identified neurological symptoms
4. Have congenital anomalies
5. Have known maternal substance abuse
6. Are to be discharged to other wards of hospitals before full oral feeding has been established
7. Have a gestational age of 37 weeks or above
8. Are being breastfed
9. If it is not possible to explain the study adequately so that informed consent can be obtained then those infants will be excluded from the study. Informed consent will be obtained from the infants carers by either the researcher or a senior member of the nursing staff.

Date of first enrolment
01/04/2005

Date of final enrolment

31/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Child Development Centre
Leeds
United Kingdom
LS9 7TF

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
Bradford South and West Primary Care Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results	results poster presentation	10/06/2008		No	No