

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/10/2017	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Kate Jones

Contact details

Child Development Centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)113 206 5838
kate.jones018@virgin.net

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 by 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