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

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Neonatal Diseases	[] Individual participant data		
	No longer recruiting Overall study status Completed		

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

Protocol serial number 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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Bradford South and West Primary Care Trust (UK)

Results and Publications

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