ISRCTN62827057 https://doi.org/10.1186/ISRCTN62827057

Randomised trial of nasal prongs versus nasal mask for the avoidance of nasal trauma with prolonged nasal continuous positive airway pressure (NCPAP) using the infant flow driver in infants <27 weeks gestation

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 02/06/2017	**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
Dr Simon Mitchell

Contact details
SMH Central Manchester & Manchester Children's University Hospitals
St Mary's Hospital for Women & Children
Oxford Road
Manchester
United Kingdom
M13 0JH
-
simon.mitchell@cmmc.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0453192065

Study information

Scientific Title
Randomised trial of nasal prongs versus nasal mask for the avoidance of nasal trauma with prolonged nasal continuous positive airway pressure (NCPAP) using the infant flow driver in infants <27 weeks gestation

Study objectives
To compare the frequency of nasal trauma during nasal CPAP delivered with an infant Flow Driver using two different methods (nasal prongs or nasal mask), both of which are in regular use on the neonatal medical unit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tameside & Glossop REC, 21/12/2006, ref: 06/Q1402/72

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases: Nasal trauma

Interventions
The study aims to examine the use of NCPAP in infants requiring support for evolving / established lung disease. It is not intended to study infants in the acute phase of their respiratory illness or within 24 hours of extubation. Following informed parental consent, infants below 27 weeks gestation will be randomised to one or three groups once they reach 48

hours of age or require continuing NCPAP more than 24 hours post extubation (whichever occurs later).

Infants will be randomised into three groups:
Group 1: (control) Nasal Prongs
Group 2: Nasal Mask
Group 3: Nasal prongs alternating with nasal mask at 8 hourly intervals

Randomisation will be by sealed numbered envelopes prepared using block randomisation by personnel not involved in the study.

The infant's nasal septum and philtrum will be assessed prior to commencing NCPAP to exclude the possibility of pre-existing skin trauma. Whilst receiving NCPAP, the condition of the infants nose will be assessed with each routine set of nursing cares, consistent with existing normal practice. For the purposes of this study, a dedicated form will be used to record these findings. Infants who are subsequently re-ventilated due to undercurrent problems or worsening lung disease will receive NCPAP via nasal prongs for the first 24 hours post extubation before reverting to their randomisation group thereafter. If there are any concerns regarding the development of nasal trauma, infants may be changed to an alternative mode of delivery (e.g. from nasal prongs to mask) or managed off CPAP, as decided by the clinical staff caring for the infant according to the infant's clinical condition and the decision and its reason recorded. Because of the nature of the intervention, blinding is not possible in this study.

Intervention Type
Device

Primary outcome measure
Frequency of the superficial skin injury (defined as discolourisation or abrasion of the skin) in each group, analysed in an intention to treat basis.

Secondary outcome measures
Proportion of infants from each group who do not continue with their allocated treatment group due to practical difficulties with the device.

Overall study start date
29/12/2006

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Infants <27 weeks gestation admitted to SMH
2. Requiring NCPAP beyond 48 hours from birth or more than 24 hours post extubation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
150

Key exclusion criteria
Added June 2008:
1. Major congenital abnormality
2. Facial or airway abnormality precluding the use of NCPAP

Date of first enrolment
29/12/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
SMH Central Manchester & Manchester Children's University Hospitals
Manchester
United Kingdom
M13 0JH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 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
Hospital/treatment centre

Funder Name
Central Manchester and Manchester Children's University Hospitals NHS Trust (UK)

Funder Name
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