

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

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		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/06/2017	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration