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Can High Flow Nasal Prongs therapy facilitate earlier establishment of full oral feeds in babies who are Nasal Continuous Positive Airway Pressure dependent at 32 weeks gestation?

Submission date
29/01/2013

Recruitment status
No longer recruiting

Registration date
14/03/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Respiratory Distress Syndrome (RDS) is a common condition in preterm infants. NCPAP (Nasal Continuous Positive Airway Pressure) is a method of ventilatory support used for these infants. It provides a continuous flow and pressure of air/ oxygen through the airways into the air sacs to prevent them collapsing during expiration and reducing the work of breathing. However it is a cumbersome mask, and it can disrupt the facilitation of breast or bottle feeding when they would otherwise be ready for it.
High Flow Nasal Prong (HFNP) therapy provides a high flow of air/ oxygen through the airways and into the air sacs. This is done through smaller nasal prongs, which cause less obstruction. Our objective is to show that when infants are ready to feed, they are more likely to feed successfully if they have the small nasal prongs as opposed to a larger mask. We aim to show that using the high flow nasal prong therapy will help them to feed sooner and to be feeding fully on breast/bottle 1 week earlier than those on NCPAP.

Who can participate?
1. Very Low Birth Weight Infants (1500g or less)
2. Born at less than 30 weeks gestation (24+0 to 29+6)
3. Neonates requiring respiratory support in the form of NCPAP at 32 weeks corrected gestational age with an oxygen requirements of less than 30%
4. Infants requiring positive end expiratory pressure (PEEP)<5 cm H2O and breathing in room air will first be offered a trial off NCPAP with no respiratory support, but if this fails they will then be eligible for randomization
5. Full enteral feeding (tube feeding)

What does the study involve?
Once eligible for the study, at 32 weeks corrected gestational age, the infant will be randomly allocated to one of two groups A or B, using a sealed envelope.
Group A will continue on NCPAP and Group B will be started on High Flow nasal prongs at 7L

/min.
Both groups will receive the same 4 hourly observation monitoring.
We have estimated that we will need to recruit 22 babies in each group (total 44 infants).
We will follow them until they reach full bottle/breast feeds.

What are the possible risks and benefits from participating?
There are no specific risks or benefits from participating.
Side effects of High flow nasal prong therapy may be clinical deterioration of the infant which will be assessed by the senior doctor on call and if needed, the infant will be resumed on NCPAP.
A possible benefit of the HFNP therapy would reaching full bottle/breast feeds earlier.

Where is the study run from?
The neonatal unit in the Coombe Women and Infants University Hospital, Dublin 8, Ireland is running this study.

When is the study starting and how long is it expected to run for?
The study is starting in February 2013 and is expected to run for 12 to 18 months.

Who is funding the study?
Coombe Women and Infants University Hospital, Ireland

Who is the Main contact?
Dr. Jan Miletin
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Contact information

Type(s)
Scientific

Contact name
Dr Jan Miletin

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
High Flow Nasal Prongs (HFNP) therapy versus Nasal Continuous Positive Airway Pressure (NCPAP) in establishing full oral feeds in Very Low Birth Weight (VLBW) infants - randomized controlled trial

Acronym
HiFlow

Study objectives
We hypothesize that infants on HFNP therapy will be established on full feeds 1 week earlier than infants on NCPAP.

Null hypothesis: is that there is no difference or less than 1 week difference between the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee, Coombe Women and Infants University Hospital, Dublin, Ireland approved on the 27th of November 2012, ref: 18 - 2012

Study design
Randomized controlled parallel group 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
Establishment of full oral bottle / breast feeding in preterm infants

Interventions

Intervention Group: Use of High Flow Nasal Prongs therapy starting at 32 weeks of corrected gestational age

Control Group: Use of Nasal Continuous Positive Airway Pressure at 32 weeks of gestation (current practice)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The establishment of full oral feeding - days from 32 weeks corrected gestational age

Secondary outcome measures
Duration of respiratory support - days from 32 weeks corrected gestational age

Overall study start date
01/02/2013

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. Very Low Birth Weight Infants (1500g or less)
2. Born at less than 30 weeks gestation (24+0 to 29+6)
3. Neonates requiring respiratory support in the form of NCPAP at 32 weeks corrected gestational age with an oxygen requirements of less than 30%
4. Infants requiring positive end expiratory pressure (PEEP)<5 cm H2O and breathing in room air will first be offered a trial off NCPAP with no respiratory support, but if this fails they will then be eligible for randomization
5. Full enteral feeding (by nasogastric or orogastric tube)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
44

Total final enrolment
44

Key exclusion criteria
Significant congenital / respiratory / cardiac / airway abnormality at the time of randomization

Date of first enrolment
01/02/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infants University Hospital
Dublin
Ireland
D 8

Sponsor information

Organisation
Coombe Women and Infants University Hospital (Ireland)

Sponsor details
Dolphin's Barn
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Sponsor type
Hospital/treatment centre

Website
http://www.coombe.ie/

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Coombe Women and Infants University Hospital (Ireland)

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?
Results article	results	01/07/2017	17/12/2020	Yes	No