ISRCTN68552342 https://doi.org/10.1186/ISRCTN68552342

A randomised controlled trial of nasal constant positive airway pressure (NCPAP) as primary therapy for respiratory distress syndrome (RDS) in very pre-term infants.

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
29/08/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0128138699

Study information

Scientific Title

Study objectives
Early intubation and surfactant therapy followed by extubation to NCPAP in preterm infants of less than 29 weeks gestation with RDS when compared to continued intubation and intermittent positive pressure ventilation (IPPV) will result in a 50% reduction in chronic lung disease (CLD) (O2 dependency at 36 weeks post menstrual age).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Neonatal Diseases: Respiratory

Interventions
Early intubation and surfactant therapy followed by extubation to NCPAP compared with continued intubation and intermittent positive pressure ventilation (IPPV)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Proportion of infants receiving added oxygen and/or respiratory support at 36 weeks post menstrual age.

Secondary outcome measures
1. Days of respiratory support
2. Days of added oxygen
3. Death
4. Pneumothorax rate
5. Sepsis rate (positive blood culture)
6. Trauma rates (nasal septal injury, tracheal stenosis)
7. Change in weight and head circumference centiles between birth and discharge (Z scores).

Overall study start date
07/10/2003

Completion date
01/03/2009

Eligibility

Key inclusion criteria
200 infants

Participant type(s)
Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
200 infants

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
07/10/2003

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Women's Hospital
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Liverpool Women's Hospital NHS 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