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Creating and maintaining functional residual capacity in preterm neonates with Respiratory Distress Syndrome (RDS)

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
03/08/2007

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
EFURCI

Study objectives
A sustained inflation with a mechanical device and early nasal continuous positive airway pressure is a more effective management strategy for RDS in preterm infants than conventional intervention with a self-inflating mask and bag, and reduces the requirement for mechanical ventilation and surfactant treatment.

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Respiratory Distress Syndrome, Preterm neonates

Interventions
Resuscitation at birth when necessary:
Group A: Prolonged inflation of 10 seconds with a mechanical device (Neopuff t-piece resuscitator) and early CPAP treatment.
Group B: Inflation with self-inflating mask and bag conform international resuscitation guidelines.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Need of endotracheal intubation within 3 days after birth.

Key secondary outcome(s))
1. Death
2. Bronchopulmonary Dysplasia (BPD)

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Preterm neonates
2. Gestational age range 25 - 32 weeks (more than 24 weeks and 6 days and not more than 32 weeks and 6 days)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

Key exclusion criteria
Antenatal diagnosed congenital anomalies of the cardio or respiratory system or anomalies incompatible with survival.

Date of first enrolment
01/04/2005

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Pediatrics, Leiden University Medical Center, J6-S, P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (The Netherlands)

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?
Results article	Results	01/08/2007		Yes	No