

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/08/2007	Condition category Respiratory	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure

Need of endotracheal intubation within 3 days after birth.

Secondary outcome measures

1. Death
2. Bronchopulmonary Dysplasia (BPD)

Overall study start date

01/04/2005

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

Age group

Neonate

Sex

Not Specified

Target number of participants

200

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
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Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details

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Sponsor type

University/education

Website

<http://www.lumc.nl/>

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (The Netherlands)

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	01/08/2007		Yes	No