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A randomised-controlled trial comparing bubble and flow driver continuous positive airway pressure in preterm infants in a resource poor setting

Submission date
09/04/2007

Recruitment status
No longer recruiting

Registration date
09/05/2007

Overall study status
Completed

Last Edited
21/04/2016

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A randomised-controlled trial comparing bubble and flow driver continuous positive airway pressure in preterm infants in a resource poor setting

Study objectives
There are two principal devices currently available for the administration of Continuous Positive Airway Pressure (CPAP). These are the flow driver and bubble systems. The flow driver is now in established use in the developed world; there is currently renewed interest in the bubble CPAP system. The systems differ substantially in cost with bubble CPAP considerably cheaper. However their efficacy has not been formally compared. In order to be adopted as a standard of care it would be necessary to demonstrate that bubble CPAP is as or more efficacious than flow driver CPAP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) committee for clinical studies, American University of Armenia, 09/03/2007

Study design
Randomised and controlled, minimisation by sex and antenatal steroids

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
Neonatal Diseases: respiratory

Interventions
Trial procedures are exactly as would be performed in the course of standard care; the only difference is the selection of type of CPAP by randomisation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Total days receiving CPAP until the time of discharge from the unit.

Secondary outcome measures
1. Infants requiring ventilation
2. Deaths
3. Pneumothorax rate
4. Facial/nasal excoriation

Outcomes will be measured at the time of discharge from the unit.

Overall study start date
24/03/2007

Completion date
30/03/2009

Eligibility

Key inclusion criteria
1. Preterm infants
2. Parental consent

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
64 babies per group

Key exclusion criteria
Major life-threatening congenital malformation.

Date of first enrolment
24/03/2007

Date of final enrolment
30/03/2009

Locations

Countries of recruitment

Armenia

Study participating centre
Mashtots ave. 22
Yerevan
Armenia
375002

Sponsor information

Organisation
Scientific Research Centre of Maternal and Child Health (Armenia)

Sponsor details
Mashtots Av. 22
Yerevan
Armenia
375002

Sponsor type
Hospital/treatment centre

Website
http://www.medlib.am/maternal/index.html

ROR
https://ror.org/00zw38x02

Funder(s)

Funder type
Charity

Funder Name
Birthlink (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No