

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	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2016	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

Completion date

30/03/2009

Eligibility

Key inclusion criteria

1. Preterm infants
2. Parental consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

https://ror.org/00zw38x02

Funder(s)

Funder type

Charity

Funder Name

Birthlink (UK)

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	01/01/2016		Yes	No