Clinical study of the effect of PEEP ventilation on right ventricular afterload in pediatric patients after cardiac surgery.

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The objective of the study is to investigate the effect of PEEP ventilation with or without a recruitment maneuver on right ventricular afterload in infants undergoing cardiac surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON32788

Source
ToetsingOnline

Brief title
PEEP and right ventricular afterload

Condition

- Congenital cardiac disorders
- Neurological disorders congenital

Synonym
cardiac performance, Mechanical ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac Index, Pediatric cardiac surgery, PEEP, Right ventricular afterload

Outcome measures

Primary outcome

Thermodilution Cardiac Index measurement with PiCCO (PiCCO system; Pulsion Medical Systems, Munich, Germany), right ventricular outflow impedance (TEE), functional residual capacity (GE Healthcare Engstrom Carestation) and arterial blood gases will be measured.

Secondary outcome

- Heart rate- Systemic arterial blood pressure- Central venous pressure - Atrial pressure

Study description

Background summary

The goal of mechanical ventilation is to establish an acceptable level of gas exchange while preventing alveolar overdistention and collapse (1-6). By applying a lung protective strategy, pro-inflammatory mediators both in the lung as well as those circulating can be reduced. The reduction of circulating levels of pro-inflammatory mediators has a positive effect on the development of multi-organ failure (1,3,4).
Mechanical ventilation in children after cardiac surgery for congenital heart disease is known to decrease pulmonary blood flow (7) and cardiac output (8). A progressive fall in cardiac index occurs with increasing PEEP levels, and the fall becomes significant at PEEP levels higher than 6 cm H2O (9). This might be explained by overdistention of aerated lung areas in the presence of atelectatic lung areas, mediated by a significant rise in pulmonary vascular resistance (9).
In contrast, we are using PEEP levels of 8 - 10 cmH2O in these children without compromising the hemodynamics. One of the explanations could be that we use recruitment maneuvers in order to avoid atelectasis and low tidal volumes (6-8

ml/kg) to avoid overdistension. In adult patients, we have shown that this ventilation strategy does not affect pulmonary vascular resistance or right ventricular ejection fraction after cardiac surgery (10, 11).
In this study we like to evaluate the effect of PEEP ventilation, with or without a recruitment maneuver, on right ventricular afterload in small children undergoing cardiac surgery on cardiopulmonary bypass (CPB), for repair of congenital heart disease.

Study objective

The objective of the study is to investigate the effect of PEEP ventilation with or without a recruitment maneuver on right ventricular afterload in infants undergoing cardiac surgery.

Study design

This study is designed as a prospective, randomised, single centre study. The total number of patients expected to be enrolled in this trial are 28.

Intervention

All patients will be ventilated For 30 minutes without PEEP, for 30 minutes with 8 PEEP and with recruitment and PEEP for 30 minutes. After each ventilation strategy CI will be measured and bloodgas will be sampled from the arterial line.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children weighing > 5 kg and older than 3 months of age
Cardiac surgery on CPB

Exclusion criteria

Residual intracardiac shunting (evaluated by TEE after CPB)
Hemodynamically instable patients.
Rhythm other than sinus
Tricuspid regurgitation
No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24525.078.08