

Influence of Positive End-Expiratory Pressure (PEEP) on Cardiac Output in Mechanically Ventilated Children

Published: 11-05-2023

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To measure cardiac output at various levels of Positive End Expiratory Pressure (PEEP).

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON54287

Source

ToetsingOnline

Brief title

IPCOM

Condition

- Cardiac disorders, signs and symptoms NEC
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym

Respiratory insufficiency; ventilator dependent

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Cardiac Output, Mechanical Ventilation, Pediatric, Ultrasonography

Outcome measures

Primary outcome

Cardiac output at different levels of PEEP

Secondary outcome

Secondary objectives included a) assessment of right ventricular parameters at different levels of PEEP, b) relationship of changes in primary outcome to respiratory mechanics and c) influence of phase of illness on these parameters.

Study description

Background summary

Due to their shared intrathoracic cavity the heart and lungs are anatomically closely related. Physiologically their combined functions provide adequate oxygen delivery to the entire body. Positive pressure ventilation, a regular intervention in the paediatric intensive care unit, influences intrathoracic pressures. Our understanding of the impact this pressure change induces is mostly based on animal studies and adult data, due to the invasive nature of diagnostic tests. Technological advances in the use of ultrasound have made it a bedside tool for the acute care physician. By using this technology, we will address the paucity in data on paediatric cardiopulmonary interactions.

Study objective

To measure cardiac output at various levels of Positive End Expiratory Pressure (PEEP).

Study design

This is a prospective observational study without invasive measurements in a 20 bed tertiary paediatric intensive care facility at the Beatrix Children's Hospital/University Medical Centre Groningen. The study will start March 1, 2021 and is completed by June 30, 2022

Intervention

Adjustment of Positive End-Expiratory Pressure (PEEP) at different levels.

Study burden and risks

Measurements will be taken solely by non-invasive means. Ultrasound is a proven, harmless diagnostic used for routine clinical practice throughout the hospital. Hence burden for the patient will be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Babies and toddlers (28 days-23 months)

Newborns

Inclusion criteria

All patients aged 0 - 5 years who are mechanically ventilated for at least 24 hours

Exclusion criteria

- Physical restraints (e.g. syndromal disorders) making it impossible to obtain required images
- Aortic stenosis
- Congenital heart defects resulting in a single ventricle physiology.
- Patients on ECMO
- Patients who are haemodynamically unstable
- premature birth with gestational age corrected for post-conceptual age less than 40 weeks
- congenital or acquired neuromuscular disorders
- congenital or acquired central nervous system disorders with depressed respiratory drive
- severe traumatic brain injury (i.e. Glasgow Coma Scale <8)
- chronic lung disease
- severe pulmonary hypertension

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2023

Enrollment: 56

Type: Anticipated

Ethics review

Approved WMO

Date: 11-05-2023

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL76731.042.21