Mechanical ventilation comparing high versus low tidal volumes in infants with or without acute lung injury.

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The aim of this study is to access the effect of low and high VT (ml/kg) on pulmonary and systemic inflammatory responses and the release of oxygen and nitrogen free radicals in the paediatric patient with and without ALI.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33002

Source
ToetsingOnline

Brief title
Mechanical ventilation comparing high versus low tidal volumes in infants.

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
lung injury due to mechanical ventilation, Ventilator Induced Lung Injury (VILI)

Health condition

Innate immuunresponse

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lung injury, mechanical ventilation, paediatric intensive care unit (PICU), tidal volume

Outcome measures

Primary outcome

The primary endpoint is the effect of low and high VT (ml/kg) on pulmonary and

systemic inflammatory responses and the release of oxygen and nitrogen free

radicals determined in deep tracheal aspirate and in plasma respectively, in

the paediatric patient with and without ALI.

Secondary outcome

Secondary endpoints are the effects of low and high VT (ml/kg) HA on

hemodynamics and pulmonary gas exchange.

Study description

Background summary

Acute lung injury (ALI) is a major cause of acute respiratory failure in children with a mortality ranging from 5-35%. Mechanical ventilation (MV) may be an important factor contributing to lung injury and the subsequent mortality by inducing the release of inflammatory mediators and the generation of oxygen and nitrogen free radicals.
Studies remain controversial whether MV by itself or only in the presence of ALI can release inflammatory cytokines.
Lung protective ventilation in order to prevent VILI has been predominantly studied in adults with ALI or ARDS and is based on a combination of limited inspiratory pressures and/or tidal volumes (V T). Clinical trials in adults have demonstrated a decrease in the inflammatory response and mortality with this strategy. Controversies exist whether patients without pre-existent lung

injury will benefit from MV with a lower VT.
To our knowledge, no published trials to date have compared the use of low VT ventilation strategies with high VT ventilation in paediatric patients with or without ALI.

Study objective

The aim of this study is to access the effect of low and high VT (ml/kg) on pulmonary and systemic inflammatory responses and the release of oxygen and nitrogen free radicals in the paediatric patient with and without ALI.

Study design

Prospective intervention cross-over study.

Intervention

After inclusion patients will be ventilated for a period of 6 hours with a PEEP of 7 cm H2O and VT of 8 ml/kg predicted body weight (*wash in period*). Following these 6 hours patients will be randomized to a group were MV will be changed first to a *lung protective* setting with PEEP of 10 cm H2O and VT of 6 ml/kg followed by a more *conventional* ventilator setting with PEEP of 4 cm H2O and VT of 10 ml/kg for a period of 6 hours or to a group starting with a *conventional* setting followed by a *lung protective* setting.

Study burden and risks

The risks of this study are negligible and the burden minimal, mostly because treatment and monitoring are part of routine care on our PICU. All patients are sedated and will have an arterial catheter in place in accordance with standard clinical care, so the patient will not experience any discomfort. There will be no direct benefit for the patients examined, but the results of this study might be of benefit for other children in the future. This study will provide important insight in the pathophysiological mechanisms underlying VILI in children and may guide future research and potentially improve ventilation strategies in children and their outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Children between the age of 2 months and 2 years admitted to the PICU and requiring MV with ALI and non ALI.
ALI is defined as:
- Bilateral infiltration seen on frontal chest radiograph
- No clinical evidence of left atrial hypertension
- Partial pressure of oxygen (PaO2)/fraction of inspired oxygen (FiO2) ratio of less than 300 mmHg
2. Patients on ventilatory support not exceeding 72 hours before inclusion of the study.
3. The expected duration of ventilation should be minimal 24 hours.
4. Patients should be ventilated by the Pressure Regulated Volume Controle (PRVC) mode.

Exclusion criteria

• No informed consent from the patient*s legal representative
• Expected survival < 2 days
• Infants < 2 months of age and infants > 2 years
• Use of corticosteroids < 6 weeks before the start or during the study
• Immunocompromised patients
• Critical pulmonary or cardiac function documented by an FiO2/PaO2 ratio < 100 mmHg or need of catecholamines for inotropic support

defined as norepinephrine > 0.5 microgram/kg/min in spite of adequate fluid resuscitation
• Pneumothorax proven by chest X-ray.
• Severe chest deformations (open sternum, flial chest, kyphoscoliosis)
• Chronic hypoxemic lung disease
• Cyanotic congenital heart disease
• Cardiac failure as a primary cause of lung disease
• Patients who had received a bone marrow or lung transplantation
• Patients with increased intracranial pressure
• Patients who had participated in other clinical trials involving acute lung injury within the preceding 30 days.
• Severe chronic liver disease (as defined by Child-Pugh class C)
• Patients after cardiac resuscitation
• Patients with a decision to limit life support.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	36
Type:	Anticipated

Ethics review

Not approved

Date:	26-03-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL27046.000.09