# Myocardial injury and function in mechanically ventilated children with and without lung injury

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a) to study if biochemical evidence of myocardial injury is associated with impaired myocardial function and to study potential determinants, and b) to study if impaired myocardial function is associated with the need for vaso-active support

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Myocardial disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34967

**Source**
ToetsingOnline

**Brief title**
The heart during mechanical ventilation

### Condition

- Myocardial disorders

**Synonym**
myocardial dysfunction, Myocardial injury

**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:** Children, Mechanical ventilation, Myocardial function, Myocardial injury

## Outcome measures

### Primary outcome

Haemodynamic indices of myocardial dysfunction (cardiac index, global ejection

fraction, dPmax).

### Secondary outcome

Need for vaso-active infusions (dopamine, dobutamine, norepinephrine)

# Study description

### Background summary

Mechanical ventilation of patients with respiratory failure has added significantly to the survival. Over the last years it has become apparent that mechanical ventilation itself induces pulmonary inflammation, termed ventilator induced lung injury (VILI). VILI has been linked to multiple organ dysfunction syndrome (MODS). The heart is one of the organs involved in MODS in patients with ALI/ARDS. Biochemical evidence of myocardial injury in critically ill mechanically ventilated children has been reported by various groups. However, the effects on myocardial function as well as the clinical consequences of these observations remain unclear and need to be studied.

### Study objective

a) to study if biochemical evidence of myocardial injury is associated with impaired myocardial function and to study potential determinants, and b) to study if impaired myocardial function is associated with the need for vaso-active support

### Study design

Prospective, observational study with invasive measurements.

### Intervention

Insertion of central arterial line with option for thermodilution

**Study burden and risks**

A special arterial line will be inserted into the femoral artery. Blood samples (2 ml) will be drawn at baseline, 24, 48 en 72 hours after enrolment. At these same time intervals haemodynamic measurements are performed. Patients are sedated during their PICU stay and receive proper analgesia. Potential risks include displacement of the indwelling arterial or central venous catheter, or haemorrhage at the injection site during insertion of the line.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

### Inclusion criteria

Presence of biochemical evidence of myocardial injury (cardiac Troponin T and/or CK-MB and/or NT pro-BNP greater than the upper limit of the reference value)
Mechanical ventilation for at least 24 hours
Presence of indwelling central venous line
Informed consent obtained from parents or legal caretakers

### Exclusion criteria

Mechanical ventilation less than 24 hours
History of congenital heart disease
Surgery for congenital heart disease
History of acquired heart disease (i.e. cardiomyopathy, myocarditis)

## Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 75 |
| Type: | Anticipated |

## Ethics review

Not approved

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|---|---|
| Date: | 22-07-2010 |
| 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 | NL29815.000.10 |