Effect of mechanical ventilation on plasma cytokine concentrations in healthy humans

Published: 16-07-2007
Last updated: 08-05-2024

Our primary goal is to compare the effects of a positive pressure mechanical ventilation with spontaneous breathing on systemic cytokine release in patients with normal pulmonary function. Secondly, the possible effects of surgery on the ventilation...

Ethical review	Approved WMO
Status	Pending
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31169

Source
ToetsingOnline

Brief title
Mechanical ventilation and cytokine release

Condition

- Immune disorders NEC
- Respiratory disorders NEC
- Nervous system, skull and spine therapeutic procedures

Synonym
ventilation-induced lung injury

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: artificial respiration, cytokines, inflammation, mechanical ventilation, ventilation-induced lung injury

Outcome measures

Primary outcome

The main study parameter is the measurement of the systemic cytokine

(IL-1alpha, IL-1beta, IL-6, IL-8, KC, TNF-alpha) release. The experiment ends

after the final blood sample has been obtained after surgery.

Secondary outcome

not applicable

Study description

Background summary

Mechanical ventilation is commonly used in the anesthetized patient during surgery or in the critically ill patient on the Intensive Care. It is however obvious that mechanical ventilation is not a physiological way of breathing (positive pressure vs negative pressure). Research revealed that mechanical ventilation in animals and in patients with ARDS can induce an inflammatory reaction with cytokine release that can contribute to the development of Ventilation Induced Lung Injury (VILI) and Multi Organ Dysfunction Syndrome (MODS). However, whether it is just the mechanical ventilation itself or a combination of interacting factors (ventilation, surgery, already damaged lungs, etc.) that is responsible for the development of VILI/MODS is not clear. For this reason, studies in humans with normal pulmonary function, comparing artificial ventilation with normal physiological, spontaneous respiration are necessary.

Study objective

Our primary goal is to compare the effects of a positive pressure mechanical ventilation with spontaneous breathing on systemic cytokine release in patients with normal pulmonary function. Secondly, the possible effects of surgery on

the ventilation induced systemic cytokine release will be studied.

Study design

In 36 healthy young patients scheduled to undergo diskectomy for intervertebral disc displacement and planned to receive general anesthesia the systemic cytokine production is measured on defined time-points before, during and after surgery.

Intervention

Patients will undergo general anaesthesia 2 hours before the scheduled start of the surgical procedure. Anaesthesia will be given according to standardized protocol. Patients are assigned to one of two patient groups. Group S will be allowed to breathe spontaneously (as much as possible, but arterial saturation will be carefully monitored and ventilation support will be provided if necessary) during the two hours before surgery, Group M will be mechanically ventilated with ventilator settings commonly used in anesthesia.

Study burden and risks

In healthy humans the effects of the prolonged anesthesia duration, if present at all, will be transient. Participation will not likely result in prolonged hospitalisation or a higher side-effect or complication rate.
This study design allows us to isolate the effect of general anesthesia. Moreover, comparing spontaneous ventilation (negative-pressure ventilation) with mechanical ventilation (positive-pressure ventilation) has never been done before. In our opinion, our study design will allow us to better investigate the impact of mechanical ventilation on cytokine release.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Between 18-65 years old, American Society of Anesthesiologists (ASA) status 1 or 2, ability to speak Dutch, body weight between 60-100 kg/s with a BMI <30 kg/m2

Exclusion criteria

Patients with pulmonary, cardiac, hepatic or renal disease or significant or instable disease of the central nervous system, patients that smoke, use of (N)SAID's within 36 hours of surgery, history of drug dependency or drug abuse, BMI >30 kg/m2 or <20 kg/m2.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17023.091.07