Ventilation with Lower Tidal Volumes as Compared to Traditional Tidal Volumes of Patients not Suffering from Acute Lung Injury.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29661

Source
NTR

Brief title
HiLoNali

Health condition

Need for prolonged mechanical ventilation.

Sponsors and support

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

1. Local inflammatory responses;

2. Local Fibrin turnover;

3. Systemic levels of biomarkers of lung injury.

Secondary outcome

Late ALI/ARDS.

Study description

Background summary

Mechanical ventilation with lower tidal volumes (6 ml/kg predicted body weight [PBW]) reduces mortality and increases the number of days without ventilator use, as compared with traditional VT (12 ml/kg PBW).
It is uncertain whether this lung-protective approach should be advocated as a standard of care in non-ALI/ARDS patients as well. We hypothesize that lung protective mechanical ventilation, using lower tidal volumes, attenuates mechanical ventilation induced pulmonary inflammation. In this trial, patients not suffering from ALI/ARDS are randomly assigned to a mechanical ventilation strategy using either lower tidal volumes or traditional tidal volumes.

Study objective

We hypothesize that lung protective mechanical ventilation, using lower tidal volumes, attenuates mechanical ventilation induced pulmonary inflammation.

Study design

N/A

Intervention

Patients are randomly assigned to receive mechanical ventilation involving either traditional VT (10 ml/kg PBW) or lower VT (6 ml/kg PBW).

All patients will undergo a minilavage every second day, preceded by blood sampling.

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Eligibility criteria

Inclusion criteria

Patients who are intubated and expected to receive mechanical ventilation for > 72 hours are eligible for the study if they do not suffer from ALI/ARDS, according to the American/European consensus criteria.

Exclusion criteria

1. > 36 hours after start of MV;

2. Are under 18;

3. Participation in other trials;

4. Pregnancy;

5. Increased uncontrolable intracranial pressure;

6. Severe chronic respiratory disease (daily medication);

7. Pneumonia;

8. Use of corticosteroids (systemic or local) or other immunosuppressive agents;

9. Pulmonary thrombo-embolism;

10. After pneumonectomy or lobectomy;

11. Previous randomisation in this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	27-08-2005
Application type:	First submission

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
NTR-new	NL119
NTR-old	NTR151
Other	: N/A
ISRCTN	ISRCTN82533884

Study results