

Pulmonary inflammation during mechanical ventilation of patients with healthy lungs

Submission date 24/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/11/2008	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR135

Study information

Scientific Title
Pulmonary Inflammation during mechanical ventilation of patients with healthy lungs: High tidal volumes versus Lower tidal volumes in patients with Healthy Lungs

Acronym

HiLoHelu

Study objectives

It is hypothesised that mechanical ventilation using lower tidal volumes and positive end expiratory pressure (PEEP) causes less local inflammation in patients with healthy lungs than mechanical ventilation using traditional tidal volumes and no PEEP.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mechanical ventilation, complications

Interventions

Mechanical ventilation using lower tidal volumes (6 ml/kg) and 10 cm H₂O PEEP versus mechanical ventilation using traditional tidal volumes (12 ml/kg) and no PEEP. Broncholaveolar lavage at T = 0 and at T = 5 hours

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Local levels of cytokines
2. Neutrophil influx
3. Activation of coagulation/inhibition of fibrinolysis
4. Ex vivo stimulation of alveolar macrophages
5. Systemic levels of biomarkers of lung injury

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/11/2005

Eligibility

Key inclusion criteria

1. Patients that are scheduled for surgical procedure of greater than 5 hours
2. Healthy pulmonary condition
3. 18 years of age
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Sepsis or uncontrolled infection
2. Acute lung injury (ALI) or acute respiratory distress syndrome (ARDS)
3. Pneumonia
4. Steroid-use
5. Diagnosis of asthma
6. Pulmonary fibrosis
7. Current thrombo-embolism
8. On daily medication for chronic obstructive pulmonary disease (COPD)
9. Mechanical ventilation for greater than 48 hours in the month prior to surgery
10. Pneumonectomy/lobectomy
11. Participation in another trial
12. Previous randomisation in present trial

Date of first enrolment

01/11/2003

Date of final enrolment

01/11/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Dept of Intensive Care
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration