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Pulmonary inflammation during mechanical ventilation of patients with healthy lungs

Submission date	Recruitment status	[ ] Prospectively registered
24/10/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/10/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/11/2008	Respiratory	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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/lebectomy

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)

Sponsor details
Department of Intensive Care
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration