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Ventilation with lower tidal volumes as compared to traditional tidal volumes of patients not suffering from acute lung injury

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 07/01/2021	**Condition category** Respiratory	

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
N/A

Study information

Scientific Title
Ventilation with lower tidal volumes as compared to traditional tidal volumes of patients not suffering from acute lung injury

Acronym
HiLoNali

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval 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
Patients are randomly assigned to receive mechanical ventilation involving either traditional Tidal Volumes (VT) (10 ml/kg Predicted Body Weight [PBW]) or lower VT (6 ml/kg PBW). All patients will undergo a minilavage every second day, preceded by blood sampling.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Local inflammatory responses
2. Local Fibrin turnover
3. Systemic levels of biomarkers of lung injury

Key secondary outcome(s))
Late ALI/ARDS.

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Patients who are intubated and expected to receive mechanical ventilation for greater than 72 hours are eligible for the study if they do not suffer from Acute Lung Injury (ALI)/Acute Respiratory Distress Syndrom (ARDS), according to the American/European consensus criteria.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Greater than 36 hours after start of Mechnical Ventilation (MV)
2. Under 18
3. Participation in other trials
4. Pregnancy
5. Increased uncontrollable 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

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

Department of Intensive Care
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010	07/01/2021	Yes	No