

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

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|--|---|---|
| Submission date 20/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/12/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/01/2021 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

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

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

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

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 measure

1. Local inflammatory responses
2. Local Fibrin turnover
3. Systemic levels of biomarkers of lung injury

Secondary outcome measures

Late ALI/ARDS.

Overall study start date

01/01/2005

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

Age group

Adult

Sex

Both

Target number of participants

200

Total final enrolment

150

Key exclusion criteria

1. Greater than 36 hours after start of Mechanical 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)

Sponsor details

Department of Obstetrics and Gynaecology

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

Study outputs

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