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# Randomised prospective European Multicenter Oscillator Acute Respiratory Distress Syndrome (ARDS) Trial

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|---|---|---|
| **Submission date**<br>23/11/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>12/05/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>13/03/2020 | **Condition category**<br>Respiratory | |

**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
Randomised prospective European Multicenter Oscillator Acute Respiratory Distress Syndrome (ARDS) Trial

## Acronym
EMOAT - European Multicenter Oscillator ARDS Trial

## Study objectives
To compare the safety and efficacy of high frequency oscillatory ventilation (HFOV) with conventional mechanical ventilation (CMV) for early intervention in adult respiratory distress syndrome (ARDS).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This study was approved by the ethical committee board of all participating institutions and was in compliance with the Helsinki Declaration.

## Study design
Randomised controlled 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
Acute respiratory distress syndrome (ARDS)

## Interventions
High frequency oscillatory ventilation (HFOV) compared with conventional mechanical ventilation (CMV).

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure

1. Cumulative survival without mechanical ventilation or oxygen dependency at 30 days
2. Mortality at 30 days

### Secondary outcome measures
1. Therapy failure
2. Crossover rate
3. Persisting pulmonary problems defined as oxygen dependency or still being on a ventilator at 30 days

### Overall study start date
01/10/1997

### Completion date
31/03/2001

## Eligibility

### Key inclusion criteria
1. Patients with ARDS, defined as:
1.1. The pressure of arterial oxygen divided by the fraction of inspired oxygen (paO2/FiO2) less than 200 mmHg
1.2. Radiographic evidence of bilateral infiltrates on chest X-ray
1.3. No evidence of atrial hypertension
2. Body weight greater than 35 kg

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
61

### Key exclusion criteria
1. Non-pulmonary terminal disease
2. Severe chronic obstructive pulmonary disease
3. Asthma and grade 3 or 4 air-leak
4. FiO2 greater than 0.80 for 48 hours
5. More than 10 days of mechanical ventilation

### Date of first enrolment
01/10/1997

### Date of final enrolment
31/03/2001

# Locations

### Countries of recruitment
France

Germany

Netherlands

United Kingdom

### Study participating centre
**P.O. Box 85090**
Utrecht
Netherlands
3508 AB

# Sponsor information

### Organisation
SensorMedics (USA)

### Sponsor details
22705 Savi Ranch Parkway
Yorba Linda
United States of America
CA 92687

### Sponsor type
Industry

### ROR
https://ror.org/03x1ewr52

# Funder(s)

### Funder type
Industry

### Funder Name
SensorMedics (USA)

# 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 | 01/08/2005 | | Yes | No |