

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

Submission date 23/11/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2020	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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 ($\text{paO}_2/\text{FiO}_2$) 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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Non-pulmonary terminal disease
2. Severe chronic obstructive pulmonary disease
3. Asthma and grade 3 or 4 air-leak
4. FiO_2 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**

United Kingdom

France

Germany

Netherlands

Study participating centre

P.O. Box 85090
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
SensorMedics (USA)

ROR
<https://ror.org/03x1ewr52>

Funder(s)

Funder type
Industry

Funder Name
SensorMedics (USA)

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	01/08/2005		Yes	No