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The oscillation for Acute Respiratory Distress Syndrome (ARDS) treated early (OSCILLATE) pilot study

Submission date	Recruitment status	[_] Prospectively registered
31/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/04/2016	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

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Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00474656

Protocol serial number
MCT-82966

Study information

Scientific Title
High frequency oscillation versus lung-protective ventilation using conventional ventilators to reduce Acute Respiratory Distress Syndrome (ARDS) mortality: a randomised, parallel, two armed, multicentre pilot trial

Acronym
OSCILLATE Pilot

Study objectives
This is a pilot study to test the feasibility of a larger trial for which we hypothesise that high frequency oscillation will reduce acute respiratory distress syndrome (ARDS) mortality compared to lung-protective ventilation using conventional ventilators.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of University Health Network, Toronto, Ontario (Canada), 03/05/2007, ref: 07-0158-B

Study design
Randomised parallel two-armed multicentre trial in therapeutic management strategy, with data analysts blinded

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory distress syndrome (ARDS)

Interventions
1. High frequency oscillation (HFO): duration of mechanical ventilation
2. Lung open ventilation: duration of mechanical ventilation

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Feasibility at one-year of study. The three feasibility outcomes for the OSCILLATE pilot study will be evaluated as follows:
1.1. We will consider adherence to our explicit mechanical ventilation protocols to be adequate if more than 80% of patients (approximately 24/30) have fewer than 10% of monitored values (excluding crossover periods) as major protocol violations
1.2. We will consider the number of crossovers to be acceptable if fewer than 10% of patients cross over to the alternate ventilator, when not allowed by protocol
1.3. We will consider patient accrual to be adequate if we recruit 60 patients from 10 sites over one-year

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/07/2008

Eligibility

Key inclusion criteria
1. Patients of either sex, 16 years and above
2. Acute onset of respiratory failure, with fewer than two weeks of new pulmonary symptoms
3. Endotracheal intubation or tracheostomy
4. Hypoxaemia: defined as a partial pressure of oxygen in arterial blood (PaO2)/fraction of inspired oxygen (FiO2) ratio of less than or equal to 200 mmHg
5. Bilateral alveolar consolidation (airspace disease) seen on frontal chest radiograph

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Remaining duration of mechanical ventilation less than 48 hours, as judged by the attending physician
2. Primary cause of acute respiratory failure judged by attending physician to be cardiac in origin
3. Lack of commitment to ongoing life support
4. Weight less than 35 kg
5. Severe chronic respiratory disease
6. Morbid obesity: defined as greater than 1 kg/cm body height
7. Neurological conditions with risk of intracranial hypertension (hypercapnia should be avoided)
8. Neuromuscular disease that will result in prolonged need for mechanical ventilation
9. Previous enrolment in this trial
10. All inclusion criteria present for greater than 72 hours
11. On high frequency oscillator (HFO) at the time of screening

Date of first enrolment
01/05/2007

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
Canada

Study participating centre
McMaster University
Ontario
Canada
L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type

Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-82966)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/02/2013		Yes	No
Results article	eligible nonenrolled patients results	01/12/2015		Yes	No