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

Submission date
31/05/2007

Registration date
31/05/2007

Last Edited
06/04/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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
NCT00474656

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/05/2007

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

Age group

Adult

Sex

Both

Target number of participants

60

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

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Sponsor information

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Sponsor type
University/education

Website
http://www.mcmaster.ca/

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, Canadian Institutes of Health Research (CIHR),
CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Canada

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	28/02/2013		Yes	No
[Results article](#)	eligible nonenrolled patients results	01/12/2015		Yes	No