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The oscillation for acute respiratory distress syndrome (ARDS) treated early trial

Submission date 30/04/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/05/2009	**Overall study status** Completed	
Last Edited 06/04/2016	**Condition category** 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
NCT01506401

Secondary identifying numbers
MCT-94829

Study information

Scientific Title
High frequency oscillation versus best current conventional ventilation to reduce acute respiratory distress syndrome (ARDS) mortality: a multicentre randomised controlled trial

Acronym
OSCILLATE

Study objectives
What is the effect of early high frequency oscillation (HFO) versus best current conventional ventilation (CV) using HFO only as rescue therapy, on all-cause hospital mortality among patients with severe early acute respiratory distress syndrome (ARDS)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University Health Network (University of Toronto) - approval pending as of 11/05/2009
2. Hamilton Health Sciences (McMaster University) - approval pending as of 11/05/2009
All other centres will seek ethics approval before recruiting participants.

Study design
Multicentre randomised controlled trial

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
Intervention group: high frequency oscillatory (HFO) ventilation using a lung-open approach and an explicit protocol.
Control group: conventional ventilation using low tidal volumes, a lung-open approach and an explicit protocol, and utilising HFO only as true rescue therapy.

Intervention Type
Procedure/Surgery

Primary outcome measure
All-cause in-hospital mortality

Secondary outcome measures
1. Mortality at other time-points (ICU discharge, 28-day)
2. Barotrauma
3. Organ dysfunction
4. Duration of mechanical ventilation
5. Duration of ICU and hospital stay
6. Quality of life at 6 months

Overall study start date
01/06/2009

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Acute onset of respiratory failure, with fewer than 2 weeks of new pulmonary symptoms
2. Endotracheal intubation or tracheostomy
3. Hypoxaemia - defined as a partial pressure of oxygen in arterial blood (PaO2)/fraction of inspired oxygen (FiO2) less than or equal to 200 mmHg on FiO2 greater than or equal to 0.5, regardless of positive end expiratory pressure (PEEP)
4. Bilateral alveolar consolidation (airspace disease) seen on frontal chest radiograph
5. Aged 16 years or over, either sex. No upper age limit.

In addition, to qualify for randomisation, patients are assessed on the following ventilator settings:
6. Mode: pressure control or volume control or pressure support

7. FiO2 greater than 0.6 (or higher if necessary to keep pulse oximetric saturation [SpO2] greater than 90%)
8. PEEP greater than 10 cm H2O (or greater if necessary to keep SpO2 greater than 90%)
9. Tidal volume 6 ml/kg predicted body weight (PBW)

After at least 30 minutes on these settings, we sample arterial blood to assess oxygenation. If PaO2 is less than or equal to 200 mmHg, the patient qualifies for randomisation; if PaO2/FiO2 greater than 200 mmHg, standardised hypoxaemia assessments are repeated at least once daily for the following 72 hours (providing the eligibility criteria are still met).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200 (actual number recruited by end of recruitment: 548)

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 circulatory overload due to, for example, congestive heart failure, hyper-resuscitation, or need for dialysis
3. Suspected pulmonary haemorrhage syndrome
4. Lack of commitment to ongoing life support (note that this does not include the presence of a "Do Not Resuscitate" order alone, if there is a commitment to ongoing life support)
5. Aged less than 16 years
6. Weight less than 35 kg
7. Severe chronic respiratory disease, as indicated by any of:
7.1. Baseline forced expriatory volume in one second (FEV1) less than 20 ml/kg predicted body weight
7.2. Pre-existing chronic interstitial lung disease with chronic interstitial infiltration on chest X-ray
7.3. Documented chronic carbon dioxide (CO2) retention (partial pressure of carbon dioxide in arterial blood [PaCO2] less than 50 mmHg) and/or chronic hypoxaemia (PaO2 less than 55 mmHg on FiO2 = 0.21)
7.4. Chronic restrictive, obstructive, neuromuscular, chest wall or pulmonary vascular disease resulting in severe exercise restriction (e.g., unable to climb stairs or perform household duties), secondary polycythaemia, severe pulmonary hypertension (mean pulmonary artery pressure [PAP] greater than 40 mmHg), or ventilator dependency
8. Morbid obesity - defined as greater than 1 kg/cm body height
9. Underlying pre-existing condition with expected 6-month mortality greater than 50%
10. Neurological conditions with risk of intracranial hypertension (where hypercapnia should be avoided)
11. Neuromuscular disease that will result in prolonged need for mechanical ventilation, including (but not limited to):
11.1. Guillain Barré syndrome

11.2. Cervical spinal cord injury
12. Previous randomisation in this trial
13. All inclusion criteria present for greater than 72 hours in study intensive care unit (ICU)
14. On HFO at the time of screening

Date of first enrolment
01/06/2009

Date of final enrolment
29/08/2012

Locations

Countries of recruitment
Canada

Chile

France

Germany

India

Saudi Arabia

Singapore

Spain

United Kingdom

United States of America

Study participating centre
Toronto Western Hospital
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Sponsor information

Organisation
Canadian Critical Care Trials Group (Canada)

Sponsor details

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Sponsor type
Research organisation

Website
http://www.ccctg.ca

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research

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