

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

Submission date 30/04/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/04/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01506401

Protocol serial number
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.

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

Study type(s)

Treatment

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(s)

All-cause in-hospital mortality

Key secondary outcome(s)

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

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

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 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 expiratory 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

United Kingdom

Canada

Chile

France

Germany

India

Saudi Arabia

Singapore

Spain

United States of America

Study participating centre

Toronto Western Hospital

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Sponsor information

Organisation

Canadian Critical Care Trials Group (Canada)

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research

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