

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

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Niall Ferguson

**Contact details**  
Toronto Western Hospital  
399 Bathurst St., 2MCL-411M  
Toronto  
Canada  
M5T 2S8  
+1 (0)416 603 6203  
n.ferguson@utoronto.ca

**Type(s)**  
Scientific

**Contact name**  
Dr Maureen Meade

**Contact details**  
McMaster University  
Faculty of Health Sciences  
Department of Clinical Epidemiology & Biostatistics, HSC-2C12  
1200 Main St W  
Hamilton

Canada  
L8N 3Z5  
+1 (0)905 525 9140 ext. 22160  
meadema@hhsc.ca

## **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.

### **Study design**

Multicentre randomised controlled trial

### **Primary study design**

Interventional

### **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 (PaO<sub>2</sub>)/fraction of inspired oxygen (FiO<sub>2</sub>) less than or equal to 200 mmHg on FiO<sub>2</sub> 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. FiO<sub>2</sub> greater than 0.6 (or higher if necessary to keep pulse oximetric saturation [SpO<sub>2</sub>] greater than 90%)
8. PEEP greater than 10 cm H<sub>2</sub>O (or greater if necessary to keep SpO<sub>2</sub> 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 PaO<sub>2</sub> is less than or equal to 200 mmHg, the patient qualifies for randomisation; if PaO<sub>2</sub>/FiO<sub>2</sub> 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 (CO<sub>2</sub>) retention (partial pressure of carbon dioxide in arterial blood [PaCO<sub>2</sub>] less than 50 mmHg) and/or chronic hypoxaemia (PaO<sub>2</sub> less than 55 mmHg on FiO<sub>2</sub> = 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**

Toronto

Canada

M5T 2S8

## **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?
<a href="#">Results article</a>	results	28/02/2013		Yes	No
<a href="#">Results article</a>	eligible nonenrolled patients results	01/12/2015		Yes	No