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

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

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

Acute onset of respiratory failure, with fewer than 2 weeks of new pulmonary symptoms
 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 Toronto Canada M5T 2S8

Sponsor information

Organisation Canadian Critical Care Trials Group (Canada)

Sponsor details

c/o Dr. John Marshall St. Michael's Hospital Toronto Canada M5M 27K

caone@smh.toronto.on.ca

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