

# Conventional positive pressure ventilation or High Frequency Oscillatory Ventilation (HFOV) for adults with acute respiratory distress syndrome

<b>Submission date</b> 13/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/05/2019	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Acute respiratory distress syndrome (ARDS) is a life-threatening condition, where the lungs are unable to provide the body with adequate oxygen to meet its' requirements. This condition is one of the most common lung complications when a person is already critically ill or seriously injured. Most patients with ARDS need to be treated using mechanical ventilation (being attached to a breathing machine) if they are to survive. While initially life-saving, mechanical ventilation using standard ventilator settings can sometimes further injure the patient's lungs and make the lung inflammation (swelling) that is the hallmark of ARDS even worse. It is believed that 1 in 12 ventilated patients with ARDS may die as a result of the effects of artificial ventilation rather than the ARDS itself. High-frequency oscillatory ventilation (HFOV) is a form of artificial ventilation where very small breaths are given very frequently (up to 10 times a second) while the patients' lungs are kept in a partly inflated state, which is thought to do less physical damage to the lungs in the long run. The aim of this study is to compare the survival and recovery rates of critically ill patients in ICU who have ARDS when treated with the Novalung R100® ventilator (HFOV) and standard mechanical ventilation.

### Who can participate?

Patients aged 16 and over in ICU who have acute respiratory distress syndrome.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are treated using the Novalung R100® ventilator until they are ready to come off ventilator support (weaning). Those in the second group are treated using the usual ventilation devices used at the hospital they are being treated in. One month later, participants in both groups are followed up in order to find out the survival rates for each group. Participants who survive also complete a number of questionnaires after 6 and 12 months in order to assess their quality of life and how their breathing is affecting their general health.

What are the possible benefits and risks of participating?

Participants who are treated with HFOV may benefit from a better recovery and a lower risk of death. For participants in both groups there is a small risk of developing ventilator-associated lung injury (where the air being pushed in and out of the lungs stretches the air sacs and airways, putting them under strain).

Where is the study run from?

Twenty-nine hospitals in England, Wales and Scotland (UK)

When is the study starting and how long is it expected to run for?

June 2007 to February 2012

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr J Duncan Young

OSCAR.Trial@nda.ox.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr J Duncan Young

### Contact details

OSCAR Trial Office

Kadoorie Centre for Critical Care Research and Education

John Radcliffe Hospital

Oxford

United Kingdom

OX3 9DU

+44 (0)1865 220621

OSCAR.Trial@nda.ox.ac.uk

## Additional identifiers

### Protocol serial number

HTA 06/04/01; Version 4 - 12 June 2007 (not final)

## Study information

### Scientific Title

A randomised controlled trial and cost-effectiveness analysis of high-frequency oscillatory ventilation against conventional artificial ventilation for adults with acute respiratory distress syndrome. The OSCAR (OSCillation in ARDS) study

### Acronym

## OSCAR: High Frequency OSCillation in ARDS

### **Study objectives**

Patients with Acute Respiratory Distress Syndrome (ARDS) treated with high frequency oscillatory ventilation will have a decreased mortality at 30 days following randomisation compared with patients treated with conventional positive pressure ventilation.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/060401>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0020/51275/PRO-06-04-01.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/51275/PRO-06-04-01.pdf)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Multi-centre randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Acute respiratory distress syndrome

### **Interventions**

Participants are randomly allocated to one of two groups:

Group 1: Conventional positive pressure ventilation

Group 2: High Frequency Oscillatory Ventilation (HFOV)

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Mortality (all causes) at day 30

### **Key secondary outcome(s)**

1. Mortality rate at first discharge from ICU
2. Mortality rate at first discharge from hospital
3. Mortality rate one year after randomisation
4. Non-pulmonary organ failures whilst treated on an intensive care unit
5. Health-related quality of life six months after randomisation
6. Health-related quality of life one year after randomisation
7. Pulmonary function one year after randomisation
8. Cognitive function one year after randomisation
9. In addition there are health care system outcomes:
  - 9.1. Primary: health cost per quality-adjusted life year gained one year after randomisation

9.2. Secondary health care system benefits: Intensive care unit length of stay, hospital length of stay

10. Utilisation of hospital resources after acute hospital discharge one year after randomisation

11. Utilisation of community care resources after acute hospital discharge one year after randomisation

**Completion date**

29/02/2012

## **Eligibility**

**Key inclusion criteria**

1. Age 16 years and over
2. Weight 35 kg and over
3. Endotracheal intubation or tracheostomy
4. Hypoxaemia defined as an arterial oxygen tension/inspired oxygen ratio (PaO<sub>2</sub>/FiO<sub>2</sub>) ratio  $\leq 26.7$  kPa (200 mmHg), with a Positive End Expiratory Pressure (PEEP)  $\geq 5$  cmH<sub>2</sub>O, determined on two arterial blood samples 12 hours apart
5. Bilateral infiltrates on chest radiograph
6. One or more risk factors for ARDS (including pneumonia, aspiration of gastric contents, inhalation injury, sepsis, major trauma, multiple transfusions, drug overdose, burn injury, acute pancreatitis, or shock)
7. Predicted to require at least 48 hours of artificial ventilation from the time of randomisation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

16 years

**Sex**

All

**Key exclusion criteria**

1. Patients who could not benefit from HFOV
  - 1.1. Patients with left atrial hypertension from any cause, diagnosed clinically or with echocardiography or pulmonary artery catheterisation
  - 1.2. Patients who have been mechanically ventilated for more than 7 days at the point of enrollment
2. Patients in whom HFOV might be hazardous
  - 2.1. Patients with airway disease expected to cause expiratory airflow limitation
  - 2.2. Patients who have had a lung biopsy or resection during this hospital admission

### 3. Administrative, practical and ethical exclusions

3.1. Patients previously enrolled in the OSCAR trial during the same hospital admission

3.2. Patients refusing consent or patients in whom relatives refuse assent

3.3. Patients who were legally incompetent prior to their hospital admission

3.4. Patients whose relatives do not understand written or verbal information for whom an interpreter is not available

3.5. Patients enrolled in another therapeutic trial in the 30 days prior to randomisation

3.6. Patients in whom active treatment has been withdrawn or withdrawal is planned

#### **Date of first enrolment**

01/06/2007

#### **Date of final enrolment**

29/02/2012

## **Locations**

#### **Countries of recruitment**

United Kingdom

England

#### **Study participating centre**

**John Radcliffe Hospital**

Oxford

United Kingdom

OX3 9DU

## **Sponsor information**

#### **Organisation**

Oxford University (UK)

#### **ROR**

<https://ror.org/052gg0110>

## **Funder(s)**

#### **Funder type**

Government

#### **Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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>	results	01/03/2015		Yes	No
<a href="#">Results article</a>	results	11/08/2016		Yes	No
<a href="#">Results article</a>	results	14/05/2019	16/05/2019	Yes	No