ISRCTN10416500 https://doi.org/10.1186/ISRCTN10416500

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

Submission date
13/06/2007

Recruitment status
No longer recruiting

Registration date
13/06/2007

Overall study status
Completed

Last Edited
16/05/2019

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 of 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
Mortality (all causes) at day 30

Secondary outcome measures
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

Overall study start date
01/06/2007

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 (PaO2/FiO2) ratio ≤26.7kPa (200 mmHg), with a Positive End Expiratory Pressure (PEEP) ≥ 5 cmH20, 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

Age group
Adult

Lower age limit

16 Years

Sex
Both

Target number of participants
1,006

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
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford University (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DU
+44 (0)1865 743003
heather.house@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/rso/contactus/ctrg.shtml

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	results	01/03/2015		Yes	No
Results article	results	11/08/2016		Yes	No
Results article	results	14/05/2019	16/05/2019	Yes	No