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Use of high frequency oscillatory ventilation for the prevention of chronic lung disease of prematurity: a multicentre trial

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 30/06/2014	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sandra Calvert

Contact details
Department of Child Health
St George's Hospital Medical School
Cranmer Terrace
London
United Kingdom
SW17 0RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9700481

Study information

Scientific Title

Study objectives
1.To determine whether early intervention with high frequency oscillatory ventilation (HFOV) reduces the incidence of chronic lung disease (CLD), defined as a persistent oxygen requirement at a corrected gestational age of 36 weeks, in preterm infants born at less than 29 weeks gestation.
2.To ensure that any short term benefits of HFOV are not associated with an increase in subsequent respiratory or neurological morbidity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic lung disease

Interventions
1. Early intervention with high frequency oscillatory ventilation (HFOV)
2. Control

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Composite variable:
1. Death before discharge from neonatal services
2. Chronic lung disease, defined as oxygen dependency 36 weeks post menstrual age (PMA)

Secondary outcome measures
1. Age at death
2. Age at final extubation
3. Failure of treatment
4. Abnormal cerebral ultrasound
5. Postnatal use of systematic steroids
6. Hearing loss greater than 60 dB
7. Pneumothorax
8. Age finally out of oxygen
9. Pulmonary haemorrhage
10. Patent ductus arteriosus
11. Retinopathy of prematurity
12. Age at discharge from hospital

Long-term outcome measures:
1. Respiratory morbidity over the first two years
2. Presence of disability at two years

Overall study start date
26/01/1998

Completion date
25/10/2003

Eligibility

Key inclusion criteria
1. Gestational age less than 29 weeks
2. Require endotracheal ventilation
3. It is considered appropriate that intensive care is continued
4. No identified major congenital malformation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
800

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
26/01/1998

Date of final enrolment
25/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Child Health
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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	29/08/2002		Yes	No
Results article	results	01/06/2014		Yes	No