ISRCTN98436149 https://doi.org/10.1186/ISRCTN98436149

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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
United Kingdom

England

Study participating centre

Department of Child Health
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

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
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

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