

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
Registration date 25/10/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/06/2014	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 Sandra Calvert

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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