ISRCTN90717641 https://doi.org/10.1186/ISRCTN90717641

Randomized Controlled Double-Blind-Study of Role of Recombinant Erythropoietin in the Prevention of Chronic Lung-Disease

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 15/12/2008	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof MI Levene

Contact details
Centre for Reproduction, Growth and Development
University of Leeds School of Medicine
The General Infirmary at Leeds
Leeds
United Kingdom
LS2 9NS

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
To evaluate the role of recombinant human erythropoietin (R-HuEpo) in reducing iron infusion, which may exacerbate free radical damage, leading to chronic lung disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized controlled double blind study

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Neonatal diseases

Interventions
Infants were randomly allocated and received either R-HuEpo (480 U/kg/wk) or placebo (4% human serum albumin) by twice weekly subcutaneous injection.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Number of days on respiratory support

Key secondary outcome(s))
Number of blood transfusions required

Completion date
06/12/1995

Eligibility

Key inclusion criteria
1. Gestational age <32 weeks and/or birthweight <1500 g
2. Requirement for mechanical ventilation and/or supplemental oxygen at birth
3. No severe renal, hepatic or coagulation disorders or major congenital malformation
4. Still require mechanical ventilation/oxygen on day 7-14 after birth

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/1993

Date of final enrolment
06/12/1995

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Reproduction, Growth and Development
Leeds
United Kingdom
LS2 9NS

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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 article	results	01/05/1997		Yes	No