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Permissive Hypercapnia in Extremely Low Birthweight Infants

Submission date 29/12/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/01/2007	**Overall study status** Completed	
Last Edited 18/04/2018	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Permissive Hypercapnia in Extremely Low Birthweight Infants

Acronym
PHELBI

Study objectives
A higher than traditional arterial carbon dioxide pressure (PaCO2) target range (permissive hypercapnia) in mechanically ventilated extremely low birth weight infants reduces the combined incidence of bronchopulmonary dysplasia or death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Ulm, 15/12/2006, ref: 230/06

Study design
Randomised controlled multicentre 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Infant respiratory distress syndrome

Interventions
Different PaCO2 target range:
Experimental intervention: PaCO2 target range 55 to 65 mmHg (day one to three of life) , 60 to 70 mmHg (day four to six), 65 to 75 mmHg (day seven to 14).
Control intervention: PaCO2 target range 40 to 50 mmHg on day one to three, 45 to 55 mmHg on days four to six, 50 to 60 mmHg on day seven to 14.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Bronchopulmonary dysplasia at 36 weeks postmenstrual age
2. Death by intention to treat

Secondary outcome measures
1. Incidence of intracranial haemorrhages
2. Incidence of air leaks
3. Duration of mechanical ventilation
4. Positive pressure support and supplemental oxygen
5. Inflammatory mediators in tracheal aspirates
6. Neurodevelopmental outcome at 18 to 24 months corrected age, per protocol ananlysis of primary outcome

Overall study start date
31/12/2007

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Extremely low birthweight infants (400 g to 1000 g) requiring mechanical ventilation within 24 hours after birth

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
830

Key exclusion criteria
Congenital malformations affecting respiratory or cardiac function or requiring surgery

Date of first enrolment
31/12/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Study participating centre
Eythstr 24
Ulm
Germany
89075

Sponsor information

Organisation
University Hospital Ulm (Universitätsklinikum Ulm) (Germany)

Sponsor details
Albert-Einstein-Allee 29
Ulm
Germany
89070
+49 (0)731 500 0
klinikumsvorstand@uniklinik-ulm.de

Sponsor type
Hospital/treatment centre

Website
http://www.uniklinik-ulm.de/

ROR
https://ror.org/05emabm63

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (Germany) (ref: Th 626/5-1)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	01/07/2015		Yes	No
Results article	results	13/03/2018		Yes	No