

Permissive Hypercapnia in Extremely Low Birthweight Infants

Submission date 29/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/04/2018	Condition category Respiratory	<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 analysis of primary outcome

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes