

Collaborative randomised controlled trial of trigger versus conventional ventilation in preterm infants with respiratory distress syndrome

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/10/2014	Condition category Neonatal Diseases	☐ 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
C/6/16-04-94/BAUMER/F

Study information

Scientific Title

Study objectives

Objectives: To investigate the effects of Patient Triggered Ventilation (PTV) compared with conventional ventilation (Intermittent Mandatory Ventilation [IMV]) in preterm infants ventilated for Respiratory Distress Syndrome (RDS).

Setting: Twenty-two neonatal intensive care units.

Design: Subjects were 924 babies under 32 weeks gestation and within 72 hours of birth ventilated for RDS for less than 6 hours. Telephone randomisation to receive either PTV or IMV. Analysis on "intention to treat" basis.

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

Neonatal diseases

Interventions

1. Trigger ventilation
2. Conventional ventilation

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Death before discharge home or oxygen therapy at 36 weeks gestation
2. Pneumothorax whilst ventilated
3. Cerebral ultrasound abnormality nearest 6 weeks
4. Duration of ventilation in survivors

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/1998

Eligibility

Key inclusion criteria

Infants of less than 32 weeks gestation, they are ventilated within 72 hours of birth, and have features compatible with respiratory distress syndrome

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

Babies with evidence of major congenital malformation or evidence of inhalational pneumonitis will be excluded

Date of first enrolment

01/11/1994

Date of final enrolment

31/03/1998

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Plymouth Hospitals NHS Trust

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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	01/01/2000		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes