

Continuous Negative Extrathoracic Pressure in neonatal respiratory failure

Submission date 08/03/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/03/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/08/2007	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof David Southall

Contact details
Academic Department of Paediatrics
University Hospital of North Staffordshire
Stoke on Trent
United Kingdom
ST4 6QG
+44 (0)1782 552575
davids@doctors.org.uk

Additional identifiers

Study information

Scientific Title

Acronym
CNEP

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neonatal respiratory failure (respiratory distress syndrome)

Interventions

Patients were randomised at four hours of age to receive either standard neonatal intensive care, or standard care plus continuous negative extrathoracic pressure (CNEP, -4 to -6 cm H₂O) applied within a purpose-designed neonatal incubator.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/11/1993

Eligibility

Key inclusion criteria

The trial was undertaken in two neonatal intensive care units, Queen Charlotte's and Chelsea Hospital (QCCH) and North Staffordshire Maternity Hospital (NSMH), between October 1989 and November 1993.

There were 244 patients: birth weight 1.53 ± 0.69 kg (mean $\pm$ SD), gestational age 30.4 ± 3.5 weeks, with respiratory failure.

Patients were considered for entry at 2 hours of age if they required additional inspired oxygen or ventilation to maintain an arterial partial pressure of oxygen (PO₂)

of ≥ 8 kPa (60 mm Hg; conversion factor 7.5) or an arterial partial pressure of carbon dioxide (PCO₂) of < 6.5 kPa at Queen Charlotte's and Chelsea Hospital (QCCH) or 8 kPa at North Staffordshire Maternity Hospital (NSMH). This latter difference was because the two participating units had different practices at the time the trial commenced.

Patients were randomised if, after a second assessment at 4 hours of age, they required $\geq 40\%$ inspired oxygen or ventilation to maintain these blood gas measurements.

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

01/10/1989

Date of final enrolment

01/11/1993

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Academic Department of Paediatrics

Stoke on Trent

United Kingdom

ST4 6QG

Sponsor information**Organisation**

University Hospital of North Staffordshire (UK)

Funder(s)

Funder type

Charity

Funder Name

Horner & Wells (UK)

Funder Name

Priory Foundation (UK)

Funder Name

Dunhill Trust (UK)

Funder Name

Moorgate Trust (UK)

Funder Name

Little Ones (UK)

Funder Name

Queen Charlotte's and Chelsea Hospital (QCCH) (UK) - use of their premises

Funder Name

North Staffordshire Maternity Hospital (NSMH) (UK) - use of their premises

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	01/12/1996		Yes	No