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Continuous Negative Extrathoracic Pressure in neonatal respiratory failure

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

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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 ± 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 ≥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