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Continuous Negative Extrathoracic Pressure in neonatal respiratory failure

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1989

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

Age group
Neonate

Sex
Both

Target number of participants
244

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
England

United Kingdom

Study participating centre
Academic Department of Paediatrics
Stoke on Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University Hospital of North Staffordshire (UK)

Sponsor details
Newcastle Road
Stoke on Trent
United Kingdom
ST4 6QG
+44 (0)1782 715444
info@uhns.nhs.uk

Sponsor type
Government

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

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	01/12/1996		Yes	No