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Comparison of non-invasive positive pressure ventilation for extubated patients who fail a single spontaneous breathing trial vs conventional weaning

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/03/2016	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0046182290

Study information

Scientific Title
Comparison of non-invasive positive pressure ventilation for extubated patients who fail a single spontaneous breathing trial vs conventional weaning

Acronym
NEXT

Study objectives
The aim of this prospective randomised controlled study is to determine if patients who are attached to a breathing machine (ventilator) by a tube in the mouth who are unable to breathe unaided (invasive ventilation) can be safely removed from the ventilator and maintained with ventilation via a face mask (noninvasive ventilation) for approximately 24 hours before withdrawal of NIV support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added September 2008: East Birmingham Local Research Ethical Committee (UK) Reference number 06/Q2703/19, May 2006.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory: Positive pressure ventilation

Interventions
Noninvasive positive pressure ventilation vs conventional weaning

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Duration of time with breathing support tube in the mouth in days

Secondary outcome measures
Length of intensive care unit and hospital stay in days

Overall study start date
13/03/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients will need to meet the criteria for reducing breathing support - will not be weaned until physiologically ready.
2. Patients will have to be on a breathing machine attached to a tube in the mouth for at least 48 hours - patients who are on a breathing machine for <48 hours are not seen as difficult to wean from a ventilator
3. Age > 18 years - patient should be able to make own legal judgements to treatment
4. Written informed consent obtained - unethical to carry out study without consent
5. Failed an attempt to try breathing without help - study only being carried out on people who have difficulty with weaning

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Added September 2008: 90

Key exclusion criteria

Added September 2008:
1. Patients who are generally not suitable for noninvasive ventilationGrade III/IV intubation
2. Gastric/oesophageal surgery on this admission
3. Patients who it has been decided would not be for re-intubation once extubated

Date of first enrolment
13/03/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthetics
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Heart of England NHS Foundation Trust (UK)

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