

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/03/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Duration of time with breathing support tube in the mouth in days

Key secondary outcome(s))

Length of intensive care unit and hospital stay in days

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

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Sex

Not Specified

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Heart of England NHS Foundation Trust (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes