

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

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| <b>Submission date</b><br>28/09/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>28/09/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>15/03/2016       | <b>Condition category</b><br>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

Dr Fang Gao

### 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.

## Primary study design

Interventional

## Study design

Randomised controlled trial

## 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  
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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