

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

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

Department of Anaesthetics  
Birmingham Heartlands Hospital  
Heart of England NHS Foundation Trust  
Bordelsey Green East  
Birmingham  
United Kingdom  
B9 5SS  
+44  
fang.smith@heartofengland.nhs.uk

## 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