

# Effect of mouth leak and humidification on non-invasive pressure support ventilation

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/07/2009	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**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**  
N0436130418

## Study information

## **Scientific Title**

### **Study objectives**

It will help to determine the appropriate treatment parameter targets and in turn the most appropriate type of ventilator for patients undergoing non-invasive ventilation for chest wall and neuromuscular weakness. In addition it will help understanding the pathogenesis of respiratory failure in such patients

### **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)**

Other

### **Study type(s)**

Not Specified

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Respiratory: Non-invasive ventilation

### **Interventions**

Randomised controlled trial; Before-after trial Random allocation to [a] treatment a [b] treatment b

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Delivered tidal volume
2. minute ventilation

### **Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2002

**Completion date**

16/10/2003

## **Eligibility**

**Key inclusion criteria**

Patients will be asked to volunteer for the study from a patient base of approximately 70 patients whom are already established on non-invasive ventilation at home.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

70

**Key exclusion criteria**

1. Change in ventilator or its settings within last 6 weeks
2. recent deterioration in condition
3. rapidly progressive disease
4. patient refusal

**Date of first enrolment**

01/06/2002

**Date of final enrolment**

16/10/2003

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Department of Respiratory Medicine (ward 14)

Leeds

United Kingdom  
LS9 7TF

## Sponsor information

### Organisation

Department of Health

### Sponsor details

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

Hospital/treatment centre

### Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

### Funder Name

None

## 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?
<a href="#">Results article</a>	results	01/09/2007		Yes	No