

# 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

**Contact name**  
Dr Justin Tuggey

**Contact details**  
Department of Respiratory Medicine (ward 14)  
Leeds Teaching Hospitals NHS Trust  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Not Specified

**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(s)**

1. Delivered tidal volume
2. minute ventilation

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

Department of Respiratory Medicine (ward 14)

Leeds

United Kingdom

LS9 7TF

**Sponsor information****Organisation**

Department of Health

**Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Leeds Teaching Hospitals NHS Trust (UK)

**Funder Name**

None

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