

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

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/07/2009	Condition category Respiratory	☐ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	01/09/2007		Yes	No