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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 21/07/2009	**Condition category** Respiratory	

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?
Results article	results	01/09/2007		Yes	No