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Non Invasive ventilation (NIV) in chronic ventilatory failure: A comparison of different modes of ventilation and an analysis of mechanisms of action

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
03/12/2008

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

RRCC820F 444354

Study information

Scientific Title

Study objectives
NIV is an effective treatment for patients with ventilatory failure due to chest wall deformity, neuromuscular disease and some patients with lung disease. NIV during sleep improves oxygenation and transcutaneous CO2 overnight, together with an improvement in sleep quality and daytime arterial blood gas tensions. It has been postulated that either control of nocturnal hypoventilation with resetting of central drive, or the relief of chronic respiratory muscle fatigue is the crucial factor determining success. Some studies have shown that the improvement in daytime arterial blood gas tensions relates to a resetting of the central respiratory controller, but not to changes in respiratory muscle function. However Schoenhofer showed that NIV used for 8 hours per day during wakefulness was just as effective at improving arterial blood gas tensions as 8 hours per day during sleep. There was a significant improvement in respiratory muscle strength, without any change in central respiratory drive, and they postulated that NIV "works" by improving respiratory muscle function.
This distinction is important since the mechanism by which NIV "works" should determine the treatment endpoint, i.e. abolition of respiratory muscle activity to achieve complete muscle rest or improved sleep efficiency and optimisation of blood gas tensions overnight to restore central respiratory drive and improve sleep quality, with consequent beneficial effects upon daytime function. In turn this may affect the choice of ventilator that is to be used; for instance pressure support ventilation (PSV), in which the ventilator is triggered into inspiration and expiration according to patient effort, results in less complete muscle rest but may be more comfortable than full pressure controlled ventilation (PCV), during which the patient is required to make no respiratory effort. However, the cost of achieving complete muscle rest may be higher inflation pressures and an imposed pattern of breathing, which patients may find uncomfortable, and that compromises sleep quality.
We plan a comparison of pressure support ventilation against volume cycled ventilation in a one month randomised crossover trial to identify the relative importance of respiratory muscle fatigue and central respiratory drive in chronic respiratory failure. This will help to identify treatment endpoints in establishing patients on home non-invasive ventilation.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Nervous system diseases: Other nervous system disease

Interventions
Pressure support ventilation vs volume cycled ventilation

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Arterial blood gas tensions (pO2, PCO2)

Secondary outcome measures
1. Exercise tolerance (shuttle walk tests)
2. Psychometric tests
3. Central respiratory drive (using ventilatory and PO.1 response to carbon dioxide)
4. Assessment of respiratory muscle strength (sniff nasal pressures).
5. Full polysomnography (sleep quality and efficiency)
6. Health status

Overall study start date
10/01/2000

Completion date
10/01/2002

Eligibility

Key inclusion criteria
Patients with established chronic respiratory failure due to chest wall deformity or neuromuscular weakness stable of home nocturnal non-invasive ventilation.

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
Added December 2008: 13

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
10/01/2000

Date of final enrolment
10/01/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
24 West End Road
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LS28 5PF

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2005		Yes	No