Initiation of chronic ventilatory support outside the hospital

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25357

Source
Nationaal Trial Register

Brief title
EOLUS

Health condition

Chronic respiratory failure.
Home mechanical ventilation
Telemedicine
Telemonitoring

Sponsors and support

Primary sponsor: University Medical Center Groningen, Department of Pulmonology
Source(s) of monetary or material Support: UMCG
MENZIS, zorgverzekeraars Nederland
VIVISOL
RESMED

Intervention

Outcome measures

Primary outcome

- Gas exchange (PaCO2 and PaO2)

Secondary outcome

- Health related quality of life

- Lung function; VC

- Costs

- Social environment

- Telemedicine

Study description

Background summary

Telecare and telecure are promising new features for chronic patients as it probably can decrease the costs of healthcare while it improves quality of life at the same time.
Nocturne was such a successful telemedicine pilot showing that patients using haemodialysis can be treated effectively outside the hospital. In the present study we want to investigate if it is possible to initiate Home Mechanical Ventilation in the patients' homes.

Points of interest during this pilot are the innovative process, the necessary telemonitoring and the organisation of the professionals.

In the Netherlands there are approximately 1600 patients (October 2007) on home mechanical ventilation of which 360 are treated in Groningen. These are mainly patients with neuromuscular diseases or ribcage abnormality who suffer from chronic respiratory failure. This number is increasing particularly for patients with Amyotrofische lateral sclerosis (ALS). Ten percent of the 360 patients who receive chronic ventilatory support in Groningen are patients with ALS, whereas this percentage was in the 2001 5%. A further increase in the future is possible caused by patients with sleep apnea.
End 2004 approximately only 20,000 patients in the Netherlands were treated with sleep apnea, while in literature it is indicated that no less than 2-4% of the population might have this. This al means that there are many patients who have not been diagnosed yet. Finally the indication for Chronic Obstructive Pulmonary Disease (COPD) is being investigated at present. If it is shown that ventilatory support is also effective in this group of patients, the demand for this therapy will further increase. Because we know that the prevalence of COPD will increase of 1995 up to 2015 with 59% at the men, whereas this even increases at the women with 123%.

Therefore new methods are needed to prepare on patients who have to start with chronic

ventilatory support.

Study objective

The goal of this study is to answer the following questions:

1. Is initiation of mechanical ventilation at home equally effective in improving gas exchange as compared to the initiation of it in the hospital?

2. Is initiation of mechanical ventilation at home equally effective in improving quality of life as compared to the initiation of it in the hospital?

3. What kind of organisation- communication and infrastructure is necessary to start home mechanical ventilation monitored by telecare?

4. Is initiation of mechanical ventilation at home more cost effective as compared to the initiation of it in the hospital?

Study design

At baseline, after 2 and 6 months.

Intervention

Sixty patients will be randomized for either initiation of ventilatory support at home (group A, n=30, intervention group) or for initiation of it in the hospital (group B, n=30).

Thereafter group A will continue ventilatory support at home and will be controlled after 8 weeks by transcutaneous assessment during the night.

Group B will be discharged and will be readmitted after 8 weeks to control the effectiveness of ventilatory support by arterial blood gasses.

During the entire programme both groups will be supervised by a nursing consultant.

Contacts

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Eligibility criteria

Inclusion criteria

1. Chronic respiratory failure.

2. Patients with neuromusculaire diseases or ribcage abnormality who suffer from complaints of alveolar hypoventilation (fatigue, headache or dyspnoea) combined with at least one of the following characteristics:

• PaCO2 > 6.0 kPa daytime.

• PaCO2 > 6.0 kPa at night.

• Orthopneu as a result of diaphragm paralysis.

Exclusion criteria

1. Invasive ventilatory support.

2. Patients admitted to a nursing home.

3. Insufficient health/social support.

4. Patients with strictly COPD.

5. Age < 18 years.

6. The physical condition and his of her social environment is sub optimal for starting non-invasive ventilation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-10-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1416
NTR-old	NTR1476
Other	ABR NL 13265.042.07 : 2007/299 METc UMCG
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A