Initiation of chronic ventilatory support outside the hospital.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38418

Source
ToetsingOnline

Brief title
EOLUS

Condition

- Neurological disorders congenital
- Neuromuscular disorders
- Thoracic disorders (excl lung and pleura)

Synonym
neuro muscular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Resmed,Vivisol ,Zorgverzekeraars Nederland (Menzis) Innovatiefonds UMCG

Intervention

Keyword: chronic ventilatory support, outside the hospital, telemonitoring

Outcome measures

Primary outcome

Primary: Gas exchange (PaCO2 en PaO2)

Secondary outcome

Secundary: Quality of life (SF 36, MRF 28, HADS, SGRQ)

Costs

Social enviremont, Intermed

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 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 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 ca. 1600 patients (October 2007) on home mechanical ventilation of which 360 is treated in Groningen. These are mainly patients with neuromuscular diseases or ribcage abnormality which suffer from chronic respiratory failure. This number shows a rising development where particularly the increase of patients with Amyotrofische lateral sclerosis (ALS) is striking over the previous years. Ten percent of the 360 patients who get 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 the slaapapneu patients . End 2004 approximately 20,000 patients in the Netherlands were treated with slaapapneu, in literature it is indicated that no less than 2-4% of the population have this. Finally the indication for Chronic Obstructive Pulmonary Disease (COPD) is at present

examined. If it is shown that also in this group chronic ventilatory support effective is, the demand for this therapy strongly will increase. 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

We want to investigate if it is possible to set up the entire process of home mechanical ventilation outside the hospital. This means practically that the patients will not be admitted to the hospital. 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?

Primary objective:
- blood gas analysis: PaCO2 and PaO2
Secondary objective:
- Health related quality of life
- costs
- social environment, Intermed
- telemedicine

Study design

Seventy six patients will be randomized, open character, for either ventilatory support at home (group A, n=38, intervention group) or for initiation of it in the hospital (group B, n=38). After this start group A will continue ventilatory support at home and will be controlled after 8 weeks by transcutaneous assessment during the night. Group B will go home and will be readmitted after 8 weeks to control the effectiveness of ventilatory support by arterial blood gasses on the ICU. Thereafter both groups will be supervised by a nurse consultant at home. At the outpatient clinic the effectiveness of ventilatory support will be performed by arterial blood gas. We believe it will take18 months to include the number of patients needed for this study.

Intervention

The start of chronic ventilatiry support will be in the hospital (standard care) or at home (telecare)

Study burden and risks

At home there is no professional caretaker permanently present to supervise the initiation of the ventilatory support in contrast to the situation if patients start their ventilatory support in hospital. However, we are trying to supervise the patients better by providing telemonitoring at home, and more important we believe that the risks are within acceptable limits as it is not dangerous for the patients if they are not ventilated adequately from the beginning. In the normal in-hospital situation it takes up to a week to get the ventilatory support at a sufficient level. The extra burden for the patients being in this project is filling in 3 different quality of life questionnaires. At baseline, after 2 and 6 months.
Other important benefits of starting ventilatory support at home are:
- It is for the patients far more convenient if they can stay at home for this period as the social and (para) medicalsupport is normally much better organised and even individually tailored which is mostly not the case in hospital.
- No arterial line at baseline and after two months
- No re-admittance after 2 months of ventilatory support

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Respiratory insufficiency

Exclusion criteria

Invasive ventilatory support
Patients admitted to a nursing home
Insufficient health/social support
Age < 18 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008

Enrollment:	76
Type:	Actual

Medical products/devices used

Generic name:	home mechanical ventilator Elisee 150
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-04-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-09-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL13265.042.07