HOMERUN
Initiation of HOme MEchanical ventilation at home in a selective group of patients with chronic hypercapnic Respiratory failUre in the Netherlands

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Patients with chronic respiratory failure currently start their ventilatory support in hospital as stated in national guideline. However, as these patients are severely disabled, a stay at the hospital for several days is experienced by many as very…

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

Summary

ID

NL-OMON43736

Source
ToetsingOnline

Brief title
HOMERUN

Condition

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

Synonym
neuromuscular disease / thoracic cage problem

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Vivisol,ZonMw

Intervention

Keyword: home mechanical ventilation, neuromuscular disease, non-invasive ventilation, telemonitoring

Outcome measures

Primary outcome

Daytime arterial carbon dioxide (PaCO2) assessed without oxygen supplementation

and ventilatory support while the patient is in sitting position, at baseline

and 6 months follow-up

Secondary outcome

- Quality of life (SF 36, MRF 28, HADS, SRI, ALSFRSr, Edmonton Symptom

Assessment Scale (ESAS), Care dependency Scale (CDS), Family Appraisal of

Caregiver Questionnaire for Palliative Care (FACQ-PC), Inventory of complicated

grief (ICG), Self-rating inventory for posttraumatic stress disorder (SRIP),

Quality of death and dying (QODD), Quality of end-of-life care from the family

perspective (Toolkit After-Death Bereaved Family Member Interview), process

evaluation and the EQ-5D)

- Lung function (if applicable)

- Telemedicine

- Costs (CRF and cost questionnaire)

- Process evaluation (interview and questionnaire)

- Palliative care and bereavement (interview and questionnaire)

Study description

Background summary

Home mechanical ventilation (HMV) in the Netherlands routinely starts in a clinical setting supervised by the regional HMV center, as recommended in the national guideline which typically requires several days, up to a week of hospitalization. Depending on the local organization this can be done on different wards varying from the intensive care unit in Rotterdam, a medium care in Maastricht and Utrecht to a specifically developed respiratory ward as part of a rehabilitation center in Arnhem. In Groningen patients are admitted to a regular respiratory ward and are transferred for one night to the intensive care unit (ICU) for nocturnal invasive blood gas analysis. These in hospital initiations of HMV are not only an expensive way of starting HMV, but also very inconvenient to this group of patients. Especially in patients who are severely disabled and around whom a home care team already exists, the initiation of HMV at home within this team would be a major improvement. In Groningen we performed a pilot study (EOLUS) in which we showed that initiation of HMV at home in a selected group of patients is equally effective and saves costs compared to inpatient initiation. Still, in EOLUS we compared only the home setting with the Groningen in hospital model and not with the other 3 models. In addition in the Dutch guideline on chronic ventilation it is stated that chronic ventilation has to be started inpatient. To change this guideline and to investigate the cost-effectiveness of initiation of HMV at home nationwide, we have to do the same comparison in the other 3 centers.
Our hypothesis is that initiation of HMV at home, by using telemonitoring, in patients with chronic respiratory failure due to neuromuscular disease (NMD) or thoracic cage problem is not inferior compared to the start of it in a hospital based setting. In addition we believe that the start at home is safe and cheaper compared to an in-hospital start. The primary outcome measure is the arterial carbon dioxide (PaCO2) while quality of life and cost-effectiveness are secondary outcomes measurements.

Study objective

Patients with chronic respiratory failure currently start their ventilatory support in hospital as stated in national guideline. However, as these patients are severely disabled, a stay at the hospital for several days is experienced by many as very uncomfortable and distressing. Secondly, at home the care of these patients is organized by a dedicated multidisciplinary team, with less variation in caregivers than in hospital. Thirdly, costs for an in hospital

start of the ventilatory support are much higher than at home.

Study design

This is a multi-center, prospective, randomized, active controlled study with a non-inferiority design. Ninety-six patients will be randomized for either initiating ventilatory support at home (home group) or in the hospital (hospital group). The home group will start their chronic ventilatory support at home being supervised by a registered nurse of a department of home mechanical ventilation (HMV) who will visit them at home. Patients who are randomized for the hospital group will start chronic ventilatory support according to the local standards of their HMV center in the hospital setting. The different steps are carefully described in a protocol in what way the ventilatory support should be adjusted (ventilator settings and therapeutic decisions) in a standardized procedure. After the start, the home group will continue chronic ventilatory support at home while the effectiveness of this treatment will be monitored only non-invasively. In the hospital group chronic ventilatory support will be monitored invasively or non-invasively during the night. In both groups, six months after the initiation of the chronic ventilatory support, the effectiveness will be assessed by arterial blood gas analysis at the outpatient clinic. In addition we will assess nocturnal transcutaneous carbon dioxide, costs, lung function and health related quality of life.

Intervention

The proposed intervention to be studied is initiation of HMV at home as compared to in hospital initiation in different settings. Recently a pilot study was performed in Groningen in which the initiation of HMV at home was compared with an in hospital start. They found that initiation of HMV at home in a selected group under strict supervision of a HMV center was effective, safe, and cost-effective compared to inpatient initiation. These results need to be duplicated and extrapolated to other models of initiation in the hospital than the Groningen model. We will therefore perform a similar study, in all four existing centers for home mechanical ventilation in the Netherlands. The ventilator being used in the home group is the same as in the hospital group. In the home group telemedicine is used to transfer information to the hospital for the delivery of clinical care. Every morning during the initiation period of HMV at home, the data of the ventilator will be sent to the hospital. The RN receives by email these digital data, not being traceable without the subject indentification code list, and will phone the patient to evaluate the results. We will use the Dyna-Vision* which is a patient monitor with built-in mobile technology that can send digital data to every location under secure conditions In this way it transfers the information collected by the ventilator and transcutaneous monitor to the hospital. The digital data comprises of ventilator settings, respiratory rate and carbon dioxide and oxygen saturation

levels.

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. The results of the pilot study EOLUS indicate that initiation of HMV at home is safe and technically feasible10.
The new intervention provides a number of important benefits compared to the usual inpatient procedure. As the patients referred for HMV are severely disabled, the care of these patients at home is organized by a dedicated multidisciplinary team, with little variation in caregivers. For example in severely disabled patients with Amyotrophic Lateral Sclerosis the start of HMV at home with the help of such a team is easier than in hospital where the number of health care providers is more variable. Another advantage of starting HMV at home is that everyone who is involved in the care of this patient starts at the same time to learn and work with HMV. In this way they get gradually adjusted to the new situation with the ventilator at home.
Transcutaneous monitoring, during the night at home, will be used to measure skin-surface PO2 and PCO2 to provide estimates of arterial partial pressure of oxygen and carbon dioxide (PaO2 and PaCO2). The SenTec* is suitable for spot check as well as long term measurements of up to 12 hours.
The ventilator being used in the home group is the same as in the hospital group. In the home group telemedicine is used to transfer information to the hospital for the delivery of clinical care. Every morning during the initiation period of HMV at home, the data of the ventilator will be sent to the hospital. The RN is able to look into this digital data, not being tracebale without the subject identification code list, and will phone the participant to evaluate the results. We will use the Dyna-Vision* and Carecom* both being patient monitors with built-in mobile technology that can send digital data to every location under secure conditions 11. In this way it transfers the information collected by the ventilator and transcutaneous monitor to the hospital. The digital data comprises of ventilator settings, respiratory rate and carbon dioxide and oxygen saturation levels.
There will be no potential risks associated with the procedure to patients participating in this clinical study.

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

The study will be set up in patients with chronic respiratory failure who were referred to a HMV center to start chronic ventilatory support.
Indication to initiate non-invasive ventilatory support in patients with a neuromuscular disease or thoracic cage abnormality who suffer from complaints of alveolar hypoventilation (fatigue, headache of dyspnoea) combined with all following elements:
-arterial carbon dioxide > 6.0 kPa daytime or arterial or transcutaneous carbon dioxide > 6.0 kPa at night or orthopnea as a result of diaphragm paralysis
-age > 18 years
-existence, of a sufficient network (social or professional) according to the supervising HMV center making initiation of HMV at home possible and safe.
-Informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation

in this study:
-Patients who previously used non-invasive ventilation
-Necessity for invasive ventilatory support
-Patients admitted to a nursing home

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):	28-07-2015
Enrollment:	96
Type:	Actual

Medical products/devices used

Generic name:	Mechanical ventilator Elisee 150 of Astral
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-03-2016

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-08-2016
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	NL51582.042.14
Other	NTR TC 4683