Validation of the ExSpiron© in patients with Amyotrophic Lateral Sclerosis; a pilot study

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Primary Objective:To validate the ExSpiron©, a device for non-invasive monitoring of respiratory volume in patients with ALS during spontaneous breathing and during NIV.Secondary Objective(s):• to observe the difference between nocturnal respiration...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON48392

Source
ToetsingOnline

Brief title
Non-invasive monitoring of respiratory volume

Condition

- Neuromuscular disorders

Synonym
Amyotrophic Lateral Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: 0

Intervention

Keyword: Amyotrophic Lateral Sclerosis, ExSpiron©, Home Mechanical Ventilation, Respiratory volume

Outcome measures

Primary outcome

To validate the ExSpiron©, a device for non-invasive monitoring of respiratory

volume in patients with ALS during spontaneous breathing and during NIV.

Secondary outcome

• to observe the difference between nocturnal respiration as compared to

respiration during daytime

• Borg score

• ALSAQ-40

• Gas exchange during the night with the transcutaneous monitor SenTec©.

• Respiratory muscle activity and patient-ventilator asynchrony during the

night and during NIV assessed with surface electromyography (EMG)

Study description

Background summary

Chronic non-invasive ventilation (NIV) started during the polio epidemic in Scandinavia and the United States. Negative pressure ventilators such as the Iron Lung, were the most commonly used mechanical ventilators throughout the 1950*s. After control of the Polio epidemic, invasive positive pressure ventilation via endotracheal tube or tracheostomy was more predominate over non-invasive ventilation. Nowadays this is the opposite, more than 80% of all patients on home mechanical ventilation (HMV) in the Netherlands are treated with NIV[1].
Types of diseases that have been successfully treated with chronic non-invasive ventilation include, neuromuscular diseases, chest wall deformity, chronic obstructive pulmonary disease and sleep related problems. Patients with these

types of diseases may develop chronic derangement of daytime gas exchange yielding daytime hypoxia and hypercapnia and chronic respiratory insufficiency is present. Patients with chronic respiratory insufficiency fail to achieve adequate ventilation and gas exchange, especially during sleep. Correction of such ventilatory and gas exchange abnormalities using non-invasive ventilation (NIV) is an increasingly popular method for improving sleep quality of life and overall survival in certain patient populations, including Amyotrophic lateral sclerosis (ALS).
ALS is a progressive neuromuscular disease and most patients develop complaints of dyspnea, fatigue, unrefreshing sleep and morning headache in the advanced stage of their diseases. NIV is commonly regarded to be a treatment that is effective in reducing these complaints. Several studies presented data regarding the effects of NIV on quality of life in patients with ALS [2][3][4]. Some were positive, while others produced more reservations. A review done by Piepers et al, concluded that studies on the use of NIV in patients with ALS differ considerably in design and endpoint definitions[5]. In daily practice it is difficult to determine what the best moment is to start NIV in ALS patients. There are objective and subjective symptoms and by judging them a clinical decision can be made. By using the ExSpiron© monitor an extra objective measurement can be added to inform patients and caregivers about the respiratory condition. This also helps to make the right decision on the right time, to start NIV, in patients with the progressive disease ALS.

Study objective

Primary Objective:
To validate the ExSpiron©, a device for non-invasive monitoring of respiratory volume in patients with ALS during spontaneous breathing and during NIV.

Secondary Objective(s):
• to observe the difference between nocturnal respiration as compared to respiration during daytime
• Borg score
• ALSAQ-40
• Gas exchange during the night with the transcutaneous monitor SenTec©.
• Respiratory muscle activity and patient-ventilator asynchrony during the night and during NIV assessed with surface electromyography (EMG)

Study design

At the outpatient clinic the pulmonologist recruits participants and the informed consent is signed a week after this visit if participants are willing to take part in the study. The pilot starts at the first day of admission of the participants on the Respiratory Care Unit (RCU) of the UMC Groningen. At daytime, TV and MV will be measured during spontaneous breathing with the ExSpiron© simultaneously with a pneumotachometer (gold-standard). After

installation of the chest pad of the ExSpiron© and the pneumotachometer, the first measurements are in sitting position (bed or (wheel)chair). Three complete cycles of ten breaths; normal breathing, slow-deep breathing and rapid-shallow breathing, need to be completed. Between each cycle, a pause is allowed. Patients may hold the pneumotachometer themselves, if unable to do so, the researcher will hold it for them. After completing this breathing sequence, it is repeated in supine position. If patients are not able to perform this in supine position, an angle of 45 degree is sufficient. After completing these cycles, a measurement of 30 minutes during spontaneous breathing will be conducted in supine and prone position without the pneumotachometer. After this measurement, the chest pad should be left in place and the EMG equipment should be installed. During the first night of admission, a full night of measurement of TV and MV will be conducted using the ExSpiron©. The SenTec© will be used for measuring oxygen saturation and carbon dioxide. Respiratory muscle activity will be recorded using the EMG equipment. Sleep quality is recorded by a polysomnography. The nurse on the ward will be instructed to start all measurements. NIV will be started as in regular care and terminated by the nurse after 4 hours or earlier when the patients doesn*t or cannot proceed further with NIV. The ExSpiron©, SenTec©, polysomnography and EMG stay in position, measurements are continued during spontaneous breathing.

Intervention

To validate the ExSpiron©, a device for non-invasive monitoring of respiratory volume in patients with ALS during spontaneous breathing and during NIV.

Study burden and risks

not applicable.

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

- Participants diagnosed with ALS requiring non-invasive ventilatory support
- Age > 20 of age; < 85 years of age
- An indication to start chronic NIV, hypercapnic respiratory failure (arterial carbon dioxide PaCO2 > 6.0 kilo pascal (kPa) measured during daytime) or orthopnoea due to diaphragm paralysis.
- Participants are able to provide feedback
- Participants that are willing to participate and are able to consent and sign the informed consent form.

Exclusion criteria

- Clinically unstable
- Acute respiratory failure
- Participants with refractory hypotension, defined as systolic blood pressure less than 90 mmHg, despite inotropic agents
- Uncontrolled cardiac ischemia or arrhythmias
- Participants suffering from metastatic or terminal cancer
- Other comorbid disease affecting respiration (ie obstructive sleep apnea, chronic obstructive pulmonary disease)
- Participants lacking functional medical decision-making

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ExSpiron 1Xi monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-12-2019
Application type:	First submission
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
ClinicalTrials.gov	NCT04089696
CCMO	NL70423.042.19