The remote self-assessment of vital capacity in patients with MND

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Primary- To determine the validity of home-based self-monitoring of VC in patients with MND.Secondary- To determine the reliability of home-based self-monitoring of VC in patients with MND.- To evaluate the feasibility of 4-weekly home-based self-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49485

Source
ToetsingOnline

Brief title
RESAVICA

Condition

- Neuromuscular disorders

Synonym
ALS, Amyotrofic Lateral Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ALS Stichting Nederland

Intervention

Keyword: Amyotrophic Lateral Sclerosis, Remote monitoring, Self-assessment, Vital capacity

Outcome measures

Primary outcome

The mean difference between the supervised VC*s and the self-assessed VC*s,

and the standard deviation of the difference (validity).

Secondary outcome

- Within patient variability of the self-assessed VC during follow-up

(reliability).

- Feasibility of a 4-weekly home-monitoring protocol.

o Adherence: number of completed home assessments divided by total number

of home assessments.

o Acceptability: Patients* perspectives on the burden, frequency and

difficulty of the home assessments.

Study description

Background summary

Patients with amyotrophic lateral sclerosis (ALS)/ motor neuron disease (MND) are burdened by frequent clinical visits, due to the complexity and severity of their disease. During these clinical visits respiratory function is assessed with pulmonary function tests (e.g. vital capacity, maximal inspiratory pressure) to determine the need for non-invasive ventilation (NIV). NIV facilitates ventilation by providing pressured air during inhalation. In current healthcare practice, patients with ALS/MND who suffer from respiratory impairment get referred to a pulmonary specialist by their rehabilitation physician or physical therapist. This often happens when patients* respiratory function has already decreased severely, to the extent that these patients need to initiate NIV within a matter of a few weeks. This has a major impact on the life of patients and their caregivers.

The late detection of reduced respiratory function is partly due to a lack of monitoring in between clinic visits. It would be valuable to have patients regularly self-assess their respiratory function from home in between clinic visits, as this will facilitate the timely detection of reduced respiratory function and possibly improve the referral to the pulmonary specialist. In addition to that, it will reduce the need for patients to visit the clinic for respiratory assessments, which reduces travel and clinical burden.

Study objective

Primary
- To determine the validity of home-based self-monitoring of VC in patients with MND.

Secondary
- To determine the reliability of home-based self-monitoring of VC in patients with MND.
- To evaluate the feasibility of 4-weekly home-based self-monitoring of VC in patients with MND.

Study design

Observational study. Patients will independently perform a pulmonary function test at home, without intervention from the researchers.

Study burden and risks

During a home visit, the patient will perform a lung function test under the supervision of a researcher and then independently perform a lung function test. During the follow-up period, patients will perform a lung function test at home at 4 different times, namely at 1 day, 4 weeks, 8 weeks and 12 weeks after the home visit. Lung function tests will be performed 3 times per session. This is a non-invasive and low-burden measurement that will not take more than 5 minutes per session. Patients will also complete two questionnaires at baseline and at follow-up 2, 3 and 4, and fill in an extra (3rd) questionnaire at the last follow-up (12 weeks). All questionnaires take no more than 5 minutes to complete.

The burden is therefore very low and there are no risks involved. Besides that, the patients are used to perform a lung function test and filling out questionnaires for healthcare purposes.

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

1. 18 years or older
2. Diagnosed with motor neuron disease (MND): amyotrophic lateral sclerosis (ALS), progressive muscular atrophy (PMA) or primary lateral sclerosis (PLS).
3. Able to perform a respiratory function test with or without caregiver assistance

Exclusion criteria

1. Tracheostomy Ventilation
2. Severe cognitive impairment

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Spirometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-06-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-10-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL73064.041.20

Study results