

Home-based monitoring of muscle strength in patients with ALS

Published: 20-07-2021

Last updated: 17-01-2025

Primary: To determine the feasibility of measuring muscle strength at home with the fixed dynamometer
Secondary: Determining the sensitivity of the fixed dynamometer to detect changes in disease progression in ALS during home measurement

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

Summary

ID

NL-OMON50814

Source

ToetsingOnline

Brief title

Home-based monitoring of muscle strength in patients with ALS

Condition

- Neuromuscular disorders

Synonym

Amyotrophic Lateral Sclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Stichting ALS Nederland

Intervention

Keyword: Amyotrophic Lateral Sclerosis, Muscle strength, Remote monitoring, Self-assessment

Outcome measures

Primary outcome

The primary outcome is the feasibility (expressed as acceptance and adherence to the 2-weekly assessment of muscle strength measurements using the PFD in the home-situation).

Secondary outcome

Secondary outcome is the rate of decline in muscle strength during the follow-up period. The trajectory of independent muscle strength measurements over time will be compared with the Revised ALS Functional Rating Scale (ALSFRS-R).

Study description

Background summary

Amyotrophic Lateral Sclerosis (ALS) is a progressive disease that affects motor neurons leading to loss of muscle strength and functional abilities. Insight into the course of muscle strength can help care providers to offer tailor-made care. Furthermore muscle strength is an important outcome measure in trials on efficacy of new therapies. Muscle strength is usually assessed with a Hand Held Dynamometer (HHD). These measurements can be easily performed in a clinical setting by physiotherapists or research nurses. However, the protocols for assessing muscle strength are often extensive and therefore time-consuming and burdensome for patients. Protocols measuring 20 muscle groups or more are no exception. In addition, these manual measurement methods are difficult to standardize and it is difficult to manually provide sufficient resistance at high forces, making this method prone to measurement errors. Fixed dynamometry can solve these problems. In fixed dynamometry, the dynamometer is placed in a fixed construction, so that the measurement can be performed in a more standardized manner and high forces can be measured.

From retrospective data research (unpublished) strength of the quadriceps muscles appeared an important predictor of life expectancy in ALS and can therefore provide insight into rate of disease progression.

The department of Rehabilitation, Physical Therapy and Sports of the UMC Utrecht has recently developed a prototype to assess strength of the quadriceps muscles using fixed dynamometry. Preliminary results in healthy subjects showed that the reliability of this fixed dynamometer is better than that of the HHD.

However, it is not yet known whether it is feasible to use the force meter independently at home for patients with ALS or PMA. In addition, it is not known whether independent measurement of muscle strength with the fixed dynamometer yields data that is sensitive enough to observe disease progression.

Study objective

Primary: To determine the feasibility of measuring muscle strength at home with the fixed dynamometer

Secondary: Determining the sensitivity of the fixed dynamometer to detect changes in disease progression in ALS during home measurement

Study design

Observational research. Patients will independently perform muscle strength measurements at home, without intervention from the researchers.

Study burden and risks

In addition to 3 visits at the patient's home by the researcher, participants will perform muscle strength measurements at home, independent of the investigator, once every two weeks for a maximum period of 24 weeks. The total duration of participation will involve a maximum of 190 minutes.

The participants are used to muscle strength measurements. Because the measurements and visits take place at home, with appropriate protective measures, participation is minimally burdensome. The results of this research can potentially contribute to the improvement of tailor-made care and to better outcome measures in scientific research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (16-17 years)

Adults (18-64 years)

Inclusion criteria

Is diagnosed with ALS or PMA

Has a minimal muscle strength of MRC 3 in at least one leg

Sufficient knowledge of the Dutch language to complete the questionnaires

Signed informed consent

Exclusion criteria

Severe cognitive impairments

Current knee pain

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	12-10-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Portable Fixed Dynamometer
Registration:	No

Ethics review

Approved WMO	
Date:	20-07-2021
Application type:	First submission
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

CCMO

ID

NL75827.041.21

Study results

Date completed: 01-07-2022

Results posted: 16-01-2024

First publication

16-01-2024