Registry of Endpoints and Validated Experiences in ALS

Published: 13-03-2018
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To determine the relationships between respiratory function, secretion management, RTIs and mortality in order to optimize medical decision-making.

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

Summary

ID

NL-OMON49001

Source
ToetsingOnline

Brief title
REVEALS

Condition

- Muscle disorders
- 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: Het bedrag komt ten gunste van de onderzoeker. Financiering van de wekelijkse follow-up en longfunctie testen is beschreven in de subsidie aanvraag Stichting ALS (Collecte busfonds; Derde geld stroom): "The Netherlands ALS Biobank and Database". Voor verdere informatie over financiering bloedgas analyse zie

subsidie aanvraag RBWH Foundation.

Intervention

Keyword: ALS, Evaluation, Respiratory

Outcome measures

Primary outcome

Rate of respiratory and functional decline, mortality and RTIs.

Secondary outcome

• Examine the relationships between rates of decline in respiratory function measures and prognosis / life expectancy / NIV initiation.

• Examine the relationship between respiratory tract infection morbidity and respiratory function.

• Examine the relationship between respiratory function and respiratory impairment symptoms.

• Correlate rates of decline in respiratory function measures and overall functional decline using the ALS functional rating scale (ALSFRS-R).

• Examine the respiratory tract infection morbidity rates.

• Examine the predictive value across a range of respiratory function constructs to predict carbon dioxide pressure (PCO2).

• Explore the potential relationships between other demographic characteristics, baseline variables, and outcome measures as defined above

Study description

Background summary

Respiratory insufficiency is the primary cause of mortality in amyotrophic lateral sclerosis (ALS). Death occurs, on average, three years after symptom onset. Therapies that improve respiratory function may have the potential to improve both quality of life and survival in ALS. A timely start of non-invasive ventilation (NIV), for example, could improve overall survival with nine months. The generation of exact evidence in support of such beneficial outcomes has been, however, challenged by variance in measurement of respiratory status. Measurement errors also complicate the medical decision-making surrounding respiratory interventions. Furthermore, due to the respiratory muscle weakness, ALS patients are more prone to respiratory tract infections. It is, however, not well document what are the relationships between respiratory measurements, initiation of secretion management and reduction of respiratory tract infections (RTIs) or mortality.

Study objective

To determine the relationships between respiratory function, secretion management, RTIs and mortality in order to optimize medical decision-making.

Study design

Longitudinal cohort study for 18 months with quarterly follow-up visits and monthly follow-up by phone or email.

Study burden and risks

patient will be asked to come to the UMC Utrecht for 7 visits, each visits will last maximum 1.5 hours. therefor, the total burden for the patient in the hospital will be 10.5 hours. Besides the hospital visits the patients will receive a monthly email with 3 questions, it will take them 5 minutes to answer those questions. Maximum time for the study: [7 x 1.5hours] + [71 x 5min] = 16 hours 30 minutes

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. Age > 18 years
2. Diagnosis of ALS according to the El Escorial criteria
3. Kings Stage 2,3 and 4A
4. Ability to give informed consent
5. Ability to complete respiratory function measurement as defined by the ability to generate consistent scores on FVC (2 valid scores within 10%).
6. Ability to correspond remotely by email /text message independently or with the assistance of a carer.

Exclusion criteria

1. Diagnosis of another respiratory condition requiring current active management (e.g. Asthma, COPD, bronchiectasis, lung cancer etc).
2. Use of NIV at time of enrolment (King Stage 4B).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-05-2018
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-01-2020
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	NL64066.041.17

Study results

Date completed: 13-07-2021

Results posted: 14-03-2023

First publication
30-09-2021