Course of recovery of respiratory muscle strength and exercise capacity in patients discharged home after mechanical ventilation and critical illness - an observational study

Published: 12-03-2019
Last updated: 09-04-2024

The aim of our study is to establish the long-term course of (recovery of) respiratory muscle strength and exercise capacity in patients who have received * 48 hours of mechanical ventilation and are discharged home.

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

Summary

ID

NL-OMON48063

Source
ToetsingOnline

Brief title
REACH - observational study

Condition

- Muscle disorders
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
ICU-acquired weakness, verminderde (adem)spierkracht na IC opname

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: SIA-RAAK subsidie en NWO promotiebeurs voor leraren

Intervention

Keyword: Aerobic capacity, Hospital discharge, Post-intensive Care Syndrome, Respiratory muscle strength

Outcome measures

Primary outcome

* Maximum inspiratory pressure (PImax) and Maximum expiratory pressure (PEmax)

as measured with the microRPM (Micro Medical)

* Step count (right leg) as measured with the 2-minute step test (TMST)

Secondary outcome

* Prevalence of decreased PImax/PEmax and functional exercise capacity in

post-ICU population discharged home.

Study description

Background summary

Patients who have been admitted to an intensive care unit (ICU) and have received mechanical ventilation, are prone to long-term physical impairments. Physical impairments described in literature are limb and respiratory muscle weakness, fatigue, decreased aerobic capacity, joint pain and neuropathies (Ohtake et al 2018, Herridge et al 2011, Stevens, Gosselink).
As more and more patients survive critical illness and ICU-stay, as a result of improvement in medical interventions, there is a larger group of patients leaving the hospital in need of aftercare in the form of rehabilitation interventions (Elliot et al 2014, Hodgson et al 2017, Iwashyna and Netzer 2012). For the physical problems as described above, the physiotherapist is often consulted (Van der Schaaf et al, 2009). Currently there is no scientific evidence on the best physical therapy interventions, although an international consensus statement was published in 2016 proposing physical therapy

interventions and a core outcome set for clinical practice (Major et al 2016).
In a project started in June 2018 and funded by SIA-RAAK ('REhabilitation after Critical Illness and Hospital discharge - REACH) a rehabilitation intervention for patients who survived critical illness and are discharged home, is developed in a Community of Practice (CoP). The CoP consists of rehabilitation professionals from several hospitals in Amsterdam and environment (OLVG Oost/West, Amsterdam UMC locations AMC and VUMC, Bovenij Hospital, Amstelland Hospital in Amstelveen and Spaarne Hospital in Hoofddorp) and first line practitioners from the field of physiotherapy, occupational therapy and dietetics working in the greater Amsterdam area. The implementation of the jointly developed intervention for patients after critical illness and hospital discharge will start in March 2019 and hospitals will start referring patients to professionals within the REACH network. This feasibility of the intervention will be evaluated through a research project for which the METC provided a waiver in July 2018 (W18_237 # 18.282).
Ongoing studies show that during recovery after critical illness not only the upper and lower limb muscles remain weakened, but also the respiratory muscles. Mainly the diaphragm is affected, but also the accessory respiratory muscles and the expiratory muscles weaken (Jonkman et al 2017). At the moment it is unclear what the influence of these weakened respiratory muscles is on the physical recovery of the patient. Currently, no additional interventions are proposed for training of the respiratory muscles, other than generalized exercise therapy. We hypothesize that the influence of weakened respiratory muscles on physical functioning and recovery is larger, than is currently understood and that respiratory muscle weakness might be present for a prolonged period of time after hospital discharge, in the post-ICU population.

Study objective

The aim of our study is to establish the long-term course of (recovery of) respiratory muscle strength and exercise capacity in patients who have received
* 48 hours of mechanical ventilation and are discharged home.

Study design

An observational study

Study burden and risks

Participants will be visited at home, at 3 time points in a six month period after hospital discharge: week 1, week 12 and week 24. During the home visit 2 physical measurements will be taken, added onto the REACH study for which a waiver was provided. No intervention will be conducted.
There are no risks associated with participation, however the physical tests might cause some fatigue as respiratory muscle strength and exercise capacity are tested. Safety criteria are set up for each of the physical tests. A

risk-benefit analysis was conducted ('Risk assessment in clinical research projects 16jan2015', AMC CRU document) and the project is determined to be of negligible risk.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Participation in the REACH study (>48 hr mechanical ventilation and ICU admission, discharged home, METC decision W18_237 #18.282)
* Provided informed consent for additional measurements for this study

Exclusion criteria

* Presence of serious cognitive or psychiatric impairments hindering compliance to the physical tests
* Inadequate understanding of the Dutch or English language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2019
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL68475.018.19