Physical function and cardiorespiratory fitness recovery in ICU survivors

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1] To explore the course of performance-based physical functional recovery at ICU admission, hospital discharge, three months post-hospital discharge and at six months post-hospital discharge of ICU survivors who have been * 48 at mechanical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49541

Source
ToetsingOnline

Brief title
Functional recovery after IC

Condition

- Other condition

Synonym
criticall ilness; post-ICU patient

Health condition

criticall ilness, multi-orgaanfalen

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiorespiratory fitness, criticall ilness, intensive care unit, physical functioning

Outcome measures

Primary outcome

1] Performance-based physical function;

Secondary outcome

2] Cardiorespiratory fitness; 3] Self-reported physical function pre-ICU admission; 4] (Health Related) Quality of life; 5] Psychological distress; 6] Self-reported daily physical activity; 7] Self-reported use of healthcare resources; 8] Participation in work and/or study; 9] Global perceived recovery in comparison to pre-ICU status; 10] Proportion of included patients who completed entire follow-up per protocol

Study description

Background summary

Prolonged mechanical ventilation in critical ill patients during intensive care unit (ICU) stay can lead to general skeletal muscle weakness and muscle dysfunction, which hampers physical functioning and cardiorespiratory fitness on the short and longer term.

Study objective

1] To explore the course of performance-based physical functional recovery at ICU admission, hospital discharge, three months post-hospital discharge and at six months post-hospital discharge of ICU survivors who have been * 48 at mechanical ventilation; 2] To explore: A] Cardiorespiratory fitness levels

three and six months post-hospital discharge; B] Self-reported physical function pre-ICU admission; C] (Health Related) Quality of life three and six months post-hospital discharge; D] Psychological distress six months post-hospital discharge; E] Self-reported daily physical activity levels three and six months post-hospital discharge; F] Self-reported use of healthcare resources three and six months post-hospital discharge; G] Participation in work and/or study three and six months post-hospital; H] Global perceived recovery in comparison to pre-ICU status at hospital discharge, three months post-hospital discharge and six months post-hospital discharge;I] Proportion of included patients who completed entire follow-up per protocol.

Study design

A single-centre, prospective cohort design.

Study burden and risks

The performance based-tests during ICU and hospital stay are part of usual care. Furthermore, the performance-based tests mimic daily life physical activities, so no extra burden associated with testing is expected during follow-up after hospital discharge when patient are at home or at a rehabilitation setting. Additionally, maximal symptom-limited exercise testing is reported to be a safe procedure, even in ICU survivors and severe deconditioned patient groups. Safety procedures will be followed before, during and after maximal exercise testing. Hence, no extra burden associated with study participation is expected by the questionnaires which do not impact or influence patient behaviour.

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

- * 18 years
- having received between * 48 hours of mechanical ventilation
- conscious and adequate (Richmond Agitation and Sedation Scale (RASS) score * 2)
- cooperative (Standard 5 Questions * 3)
- free from delirium for at least 24 hours (i.e. being eligible to test)

Exclusion criteria

- pre-existing orthopaedic or neuromuscular comorbidity that affects adequate physical function assessment
- central neurologic or spinal cord pathology
- non-ambulatory prior to ICU admission
- receiving palliative care
- Insufficient understanding of the Dutch language
- Unable to give written informed consent to participate in the study
- Not eligible to perform maximal exercise testing at 3-6 months post-ICU discharge using the American College of Sports Medicine screening form (ACSM, 1998)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2019
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	29-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	07-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL68583.058.18