Prediction and Outcome of Weakness in the Intensive Care Unit.

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To develop a screening test to predict ICU-AW at an early stage in patients admitted to the ICU. Also by prospectively following the patient group in time, this study aims to describe the natural history and functional limitations in patients...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON36528

Source
ToetsingOnline

Brief title
POWER study.

Condition

- Ancillary infectious topics
- Neuromuscular disorders

Synonym
Intensive care unit - acquired weakness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Center for Translational Molecular Medicine

Intervention

Keyword: criticall illness, outcome, sensitivity/specificity, weakness

Outcome measures

Primary outcome

Sensitivity and specificity of the different electrophysiological studies for

predicting ICU-AW.

Secondary outcome

Functional impairments after 3,6 and 12 months; risk factors for developing

ICU-AW; feasibility of the different electrophysiological studies.

Study description

Background summary

Intensive care unit - acquired weakness (ICU-AW) is a frequent and important complication of critical illness. Patients suffer from severe weakness affecting extremities but also respiratory muscles. ICU-AW causes increased mortality, longer duration of mechanical ventilation and protracted recovery after a critical illness. The most important risk factors for development of ICU-AW are sepsis and the systemic inflammatory response syndrome (SIRS). Diagnosing ICU-AW is difficult. Due to concomitant disorders of consciousness conventional diagnostic methods for diagnosing weakness, i.e the neurological examination, is not possible at an early stage. This leads to a delayed diagnosis of ICU-AW which hampers clinical decision making on for example tracheostomy and rehabilitation strategies.

Study objective

To develop a screening test to predict ICU-AW at an early stage in patients admitted to the ICU. Also by prospectively following the patient group in time, this study aims to describe the natural history and functional limitations in patients suffering from ICU-AW.

Study design

Prospective cohort study.

Study burden and risks

Depending on when the patient awakens, he or she will be screened once or multiple times. Every screening examination will take about 10 minutes. After awakening, a clinical neurological examination will be preformed also taking about 10 minutes. If the patients consents to partcipate in the follow up study, he or she will be contacted via telephone three times. One interview at 3, 6 and 12 months after discharge. Every interview will take about 15 minutes to complete.

Electrophysiological studies used in this project are used and accepted worldwide. For this project extra stringent safety requirements have been developed which will be evaluated before every examination. The risk for the patient will be negligible.

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

>2 days on mechanical ventilation

Exclusion criteria

Stroke as reason for admission, quadriplegia due to spinal cord disorder, out of hospital cardiac arrest, neuromuscular disorder as reason for admission

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

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	NL33385.018.10