Neuromuscular Ultrasound in Critical Illness

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To evaluate whether neuromuscular ultrasound discriminates between patients with and without ICU-AW.To detect differences between patients that do and do not have ICU-AW in order to determine relevant cut-offs which can be used in future diagnostic...

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

Summary

ID

NL-OMON41662

Source
ToetsingOnline

Brief title
ULTRA

Condition

- Ancillary infectious topics
- Neuromuscular disorders

Synonym
Intensive Care Unit - aquired weakness

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intensive Care, Muscle, Nerve, Ultrasound

Outcome measures

Primary outcome

Difference in gray-scale value as measures of echointensity on standardized cross-sectional ultrasonographic views of five muscle groups on one side (biceps brachii, forearm flexor group, quadriceps femoris, tibialis anterior, and diaphragm) in patients with ICU-AW and patients without ICU-AW.

Secondary outcome

- Differences in standard deviation of the gray scale values as a measure of homogeneity of the five muscle groups (biceps brachii, forearm flexor group, quadriceps femoris, tibialis anterior, and diaphragm) between patients with ICU-AW and patients without ICU-AW.
- Differences in cross-sectional muscle thickness as measure of muscle atrophy of the five muscle groups (biceps brachii, forearm flexor group, quadriceps femoris, tibialis anterior, and diaphragm) between patients with ICU-AW and patients without ICU-AW.
- Differences in vascularity of the five muscle groups (biceps brachii, forearm flexor group, quadriceps femoris, tibialis anterior, and diaphragm) between patients with ICU-AW and patients without ICU-AW.
- Differences in gray*scale value and area and vascularity on standardized cross-sectional ultrasonographic views of median nerve and peroneal nerve (at one side) between patients with ICU-AW and patients without ICU-AW.
- Patient and control characteristics: age, sex, body weight, length, medical

history, pre-admission performance.

- Clinical data: illness severity, diagnosis, laboratory data, microbiological

data, radiological data, strength measurements.

- Number of patients and controls with indeterminate results, missing results

and outliers of the index test.

Study description

Background summary

Intensive Care Unit-acquired weakness (ICU-AW), a frequently occurring complication of critical illness, can be caused by muscle dysfunction (critical illness myopathy; CIM), nerve dysfunction (critical illness polyneuropathy; CIP) or a combination (critical illness neuromyopathy; CINM). Differentiation between these disorders is difficult with current diagnostic methods. Ultrasound examination of the neuromuscular system has been shown to improve diagnostic accuracy in various neuromuscular diseases and have brought new insights in the pathophysiology of these diseases. However, diagnostic accuracy of ultrasound examination for ICU-AW has not been investigated. As an initial step, we will perform a prospective cross-sectional study, in which we will assess patients admitted at the ICU with critical illness who require mechanical ventilation for at least two days. When patient cooperation allows, the reference standard will be strength monitoring according to the medical research council scale to assess the presence of ICU-AW as part of routine care. Next, blinded to the reference standard, neuromuscular ultrasound examination will be performed. If this initial study shows that ultrasound is able to discriminate between patients with and without ICU-AW, the next step will be ultrasound monitoring before strength assessment is feasible to assess whether ultrasound parameters are able to predict ICU-AW at an early stage.

Study objective

To evaluate whether neuromuscular ultrasound discriminates between patients with and without ICU-AW.

To detect differences between patients that do and do not have ICU-AW in order to determine relevant cut-offs which can be used in future diagnostic accuracy studies to discriminate between these patient groups.

Study design

Prospective, cross-sectional survey of the study population

Study burden and risks

ICU-AW can only be investigated in the intensive care. Ultrasound is a non-invasive, painless, and harmless investigation, which can be performed at the bedside at the ICU, thus having a negligible risk and burden for the patient. Also patients with in-dwelling metals such as pacemakers can be evaluated without any harm. The investigations will take around 45 min. The ultrasound technique has proven its usefulness in several neuropathies and myopathies, but as yet has been sparsely studied in critical illness. Although the participants of this study will not benefit from this study, the possible future improvement of the diagnostic process of ICU-AW can lead to tailored care. The need for rehabilitation, the avoidance for medication detrimental to muscle or nerve and early tracheostomy are examples of possible benefits when ultrasound may be able to differentiate between patients who do and do not develop ICU-AW.

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

Adult patients newly admitted to the ICU of the Academic Medical Center
- Mechanical ventilation for at least 48 hours
- Diagnosis of ICU-AW or absence of ICU-AW, according to consensus guidelines, made by physical therapist as part of routine care
- At least one arm and one leg available for testing

Exclusion criteria

Neuromuscular disorder as reason for admission; Stroke (ischemic, hemorrhagic or subarachnoid) as reason for admission; Quadriplegia due to spinal cord syndrome in medical history or as reason for admission; Out of hospital cardiac arrest as reason for admission; Traumatic brain injury as reason for admission
Known intracerebral space occupying lesion
Poor functional status before admission (modified Rankin score 4 or 5)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2013
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	15-07-2013
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

ID: 27105
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41156.018.12
OMON	NL-OMON27105