Neuromuscular ultrasound in patients with and without ICU-acquired weakness

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27105

Source
Nationaal Trial Register

Brief title
ULTRA

Health condition

ICU-acquired weakness, CIP, CIM, CINM, critical illness polyneuropathy, critical illness myopathy, criticall illness neuromyopathy

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Department of Intensive Care and Department of Neurology
Source(s) of monetary or material Support: Academic Medical Center, Amsterdam
Department of Intensive Care and Department of Neurology

Intervention

Outcome measures

Primary outcome

Difference in gray-scale value as measures of echointensity on standardized cross-sectional ultrasonographic views of five muscle groups 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 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 between patients with ICU-AW and patients without ICU-AW.

- Differences in area and vascularity on standardized ultrasonographic views of median nerve and peroneal nerve.

Study description

Background summary

Intensive Care Unit-acquired weakness (ICU-AW), a frequently occurring complication of critical illness. Ultrasound examination of the neuromuscular system has been shown to improve diagnostic accuracy in various neuromuscular diseases. However, diagnostic accuracy of ultrasound examination for ICU-AW has not been investigated.

The aim of this study is to evaluate whether neuromuscular ultrasound discriminates between patients with and without ICU-AW.
In this prospective cross-sectional survey, adult patients admitted to the ICU of the Academic Medical Center, who require mechanical ventilation for at least two days, will be included. The presence of ICU-AW will be assessed by the attending physiotherapist, using the Medical Research Council score. Thereafter, an extensive neuromuscular ultrasound examination will be performed.

The main study endpoint is the difference in gray-scale value, as measures of echointensity, on standardized cross-sectional ultrasonographic views of five muscle groups in patients with ICU-AW and patients without ICU-AW.

Study objective

Neuromuscular ultrasound can discriminate between patients with and without ICU-AW

Study design

Single timepoint for neuromuscular ultrasound just after valid muscle strength assessment

Intervention

Muscle strength will be investigated by the attending physiotherapist, using the Medical Research Council (MRC) sumscore to assess the presence of ICU-AW.
Next, blinded to the strength evaluation, neuromuscular ultrasound examination will be performed.

Contacts

Public
Academic Medical Center (AMC),
Department of Neurology,
P.O. Box 22660
C. Verhamme
Meibergdreef 9
Amsterdam
The Netherlands
+31 (0)20 5663856
Scientific
Academic Medical Center (AMC),
Department of Neurology,
P.O. Box 22660
C. Verhamme
Meibergdreef 9
Amsterdam
The Netherlands
+31 (0)20 5663856

Eligibility criteria

Inclusion criteria

-Adult patients newly admitted to the ICU

-Mechanical ventilation for at least 48 hours

-Feasible evaluation of ICU-AW according to international standard with the MRC scale

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)

- >= 2 extremities available for testing

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	23-07-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41662
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3925
NTR-old	NTR4148
CCMO	NL41156.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41662

Study results

Summary results
N/A