Small fibre neuropathy in critical illness

Published: 28-11-2011
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to investigate if small nerve fibres are affected in patients with ICU-AW

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

Summary

ID

NL-OMON35607

Source
ToetsingOnline

Brief title
SENSS study

Condition

- Ancillary infectious topics
- Peripheral neuropathies

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 Translation Molecular Medicine

Intervention

Keyword: critical illness, Intensive Care Unit acquired weakness, skin biopsy, small fibre neuropathy

Outcome measures

Primary outcome

- the difference in intra-epidermal nerve fibre density measured using

bright field immunohistochemistry between patients with ICU-AW and normative

values matched for age and gender known in the literature

Secondary outcome

- correlation between muscle strength and IENF density

- correlation between clinical markers (e.g sensory disturbances) for small

nerve fibre function and IENF density

- correlation between temperature discrimination threshold and IENF density

- deposition of various inflammatory markers using immunohistochemistry

- density of post ganglionic sympathetic fibres

Study description

Background summary

Intensive Care Unit-acquired weakness, 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. Skin biopsy is a valuable tool for diagnosis and understanding of various neuromuscular disorders. Its use has not been investigated in Intensive Care Unit-acquired weakness because it is not known if small nerve fibres are affected.

Study objective

to investigate if small nerve fibres are affected in patients with ICU-AW

Study design

observational cohort study

Study burden and risks

patients with diagnosed with ICU-AW will be investigated once after day 25 after ICU admission using a skin biopsy and several clinical markers of small nerve fibre function and general markers of neurologic function. Skin biopsy is safe method when the proper techniques are employed. If small nerve fibre damage is found, subsequent studies can investigate its usability to improve diagnostics and understanding of 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

diagnosed with Intensive Care Unit - acquired weakness
available in het AMC for investigation 25 days after ICU admission

Exclusion criteria

risk factor for small fibre neuropathy
bleeding disorder
delayed wound healing
leukopenia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	28-11-2011
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	NL38545.018.11