Prevalence of neuropathic pain in one year survivors after intensive care admission

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON45349

Source
ToetsingOnline

Brief title
Neuropathic pain after critical illness

Condition

- Peripheral neuropathies

Synonym
Nerve pain

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Critical illness, Intensive care unit, Neuropathic, Pain

Outcome measures

Primary outcome

The main study parameter is the prevalence of neuropathic pain in the study population as measured with the Douleur Neuropathique 4 (DN4) questionnaire. Besides 7 questions, this questionnaires contains also 3 items of short physical examination of the painful area.

Secondary outcome

Not applicable.

Study description

Background summary

In critically-ill patients who have survived an intensive care unit (ICU) admission, the reported prevalence of chronic pain is substantially higher than in the general population. However, its etiology has not been studied. Furthermore, it is unknown whether this pain has primarily nociceptive or neuropathic characteristics. Discriminating between neuropathic pain and other pain will provide clues regarding underlying pathophysiological mechanisms and may guide improved treatment and preventive measures.

Study objective

Our primary objective is to determine the prevalence of neuropathic pain within one-year ICU survivors. A secondary objective is to compare patient and disease characteristics between patients reporting neuropathic versus other pain, in order to gain insight in possible risk factors for the development of neuropathic pain.

Study design

Given the (almost complete) lack of prior knowledge about the topic, our study is designed as an observational pilot study. In a subgroup of patients

reporting pain one year after ICU discharge according to a standard written survey that is already routinely distributed among ICU survivors in the University Medical Center Utrecht (UMCU), we will identify individuals with (possible) neuropathic symptoms using an additional questionnaire and simple physical examination.

Study burden and risks

The presence of pain in one-year ICU survivors is determined by analysis of the routine follow-up questionnaire used at the ICU of the UMCU (METC protocol number 10-006). Patients with pain one year after ICU stay will be contacted by telephone and asked if they want to participate in a study investigating the nature of their pain. After obtaining spoken informed consent, patients will be visited at home. After obtaining written informed consent, the DN4 questionnaire will then be used to determine presence or absence of neuropathic pain. Patients are also asked to rate the intensity of their pain on the numeric rating scale (NRS) and visual analogue scale (VAS). To determine physical, and especially muscle, function, hand grip strength will be measured using a grip strength dynamo meter. Furthermore, some other questionnaires will be filled out during this visit; the EuroQol 5D-3L (EQ5D) investigating health-related quality of life (HRQoL), the hospital anxiety and depression scale (HADS), and the impact of event scale (revised) (IES-R) investigating symptoms of post-traumatic stress. These questionnaire and measurements will take approximately 30-45 minutes and are completely non-invasive.

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

1. Patient was 18 years or older at the time of ICU admission.
2. Length of stay in the ICU > 48 hours.
3. Recent address and vital (survivorship) status confirmed by follow-up survey.
4. Spoken informed consent from the patient is obtained during a telephone call
Subsequent written informed consent from patient will be obtained during the home visit (before performing measurements).

Exclusion criteria

Patients who are not competent to provide informed consent (i.e. patients with severe cognitive dysfunction).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2017

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL60310.041.16