Monitoring palliative sedation by community nurses: inter-rater reliability of the Richmond Agitation and Sedation Scale.

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What is the inter-rater reliability of the RASS by monitoring palliative sedation by community nurses?

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38583

Source
ToetsingOnline

Brief title
Monitoring palliative sedation by community nurses: ICC of the RASS.

Condition

- Other condition

Synonym
Palliative sedation

Health condition

Het onderzoek betreft terminale patienten die gesedeerd worden (levenverwachting korter dan twee weken)

Research involving

Human

Sponsors and support

Primary sponsor: ZZG Zorggroep
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: Community nurses, Inter-rater reliability, Palliative sedation, RASS

Outcome measures

Primary outcome

Intraclass Correlation Coefficient (ICC)

Secondary outcome

inapplicable

Study description

Background summary

Palliative sedation is defined as the intentional lowering of consciousness of a patient in the last stage of life. The patient is dying and experiences unbearable suffering. (Royal Dutch Society for the Advancement of Medicine [KNMG], 2009).

When a palliative sedation takes place within the home of the patient, community nurses have an explicit role in identifying, observing, measuring and reporting the course of the sedation. (KNMG, 2011). In order to describe the depth of sedation, the nurse can use a sedation score (KNMG, 2009). There is no golden standard for monitoring the depth of a palliative sedation (Arévalo, Brinkkemper, van der Heide, Rietjens, Ribbe, Deliens, Lure, Zuurmond & Pérez, 2012).

Arévalo et al. studied four sedation scales in 2012. These scales were validated within an ICU setting. This study showed that the Richmond Agitation Sedation Scale (RASS) is the most reliable and valid instrument to monitor sedation in the palliative setting. The RASS was also the least time consuming scale. But this study was done in a clinical setting.

Problem
There is no validated scale for monitoring sedation within a homecare setting.

The study of Arévalo et al. (2012) took place in a clinical setting, being hospices and nursing homes. However, the everyday practice of palliative care in the homecare setting differs from the practice in the clinical setting.
The frequency of monitoring sedation in the homecare setting is lower compared to the clinical setting. A community is a generalist and works on her own. To improve the quality of monitoring palliative sedation, it is important to study the RASS in a homecare setting. It should be demonstrated that the inter-rater reliability is sufficient. Based on the research results, the RASS could be implemented within the homecare.

Study objective

What is the inter-rater reliability of the RASS by monitoring palliative sedation by community nurses?

Study design

Prospective observational study

Study burden and risks

This study will show no risks for the patients and/or his or her representative that are included. During this study no interventions or invasive tests will be performed.
The burden for the patient and/or his/her representative will be the occasionally administering of a physical stimulus (shaking the shoulder or rubbing the sternum). This stimulus will only be administered if a reduced consciousness is observed. The burden for the patient and/or their representative is best described as a daily extra nurse in their home for about ten minutes.
This study will include the legally incapable, i.e. patients who are legally incapable as result of delirium or unconsciousness caused by progression of the disease. Given the purpose of the study and the nature of the care being delivered, the measurement of the level of consciousness, it is desirable that these clients are included within the studies population. The observational nature of the study prevents unnecessary burden in this vulnerable population.

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

•The indication for palliative sedation is determined by a general practionar in accordance with the national guidelines for sedation from the Royal Dutch Medical Association;
• The patient is 18 year or older;
• The sedation takes place in the home of the patient;
• The patient receives homecare from the community nurses from the ZZG Zorggroep. This care includes the assesment op the palliative sedation within the study period;
• The general practionar agrees that the patient and/or his representative will be approaced for participation in the study;
•The patient and/or his representative agrees with participation in the study and has signed the informed consent.

Exclusion criteria

No exclusion criteria

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL44376.091.13