Objective evaluation of sedation, pain and delirium in palliative care patients in a nursing home; pilot study

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

Summary

ID

NL-OMON31858

Source
ToetsingOnline

Brief title
Evaluation of sedation, pain and delirium in palliative care; pilot

Condition

- Other condition

Synonym
comfort, sedation

Health condition

palliatieve zorg

Research involving
Human

Sponsors and support

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

Intervention

Keyword: delirium, elderly patients, palliative care, sedation

Outcome measures

Primary outcome

Primary research question:

Can comfort be monitored in palliative care patients in a nursing home by measuring sedation, pain and delirium?

Secondary outcome

Secundary research question:

Is the Bispectral index (BIS) monitor valid to measure depth of sedation in palliative care patients in a nursing home and associated with the given medication?

Is a change in BIS score correlated to a change in medication given to influence the depth of sedation?

Study description

Background summary

Near the end of life various symptoms can be seen. Pain and delirium are two symptoms that frequently accompany the nearing death.
The assessment of pain and delirium in nursing home patients and palliative care patients is often poor. Therefore, several tools to evaluate symptoms have been developed. For pain the Rotterdam Elderly Pain Observation Scale (REPOS) is a promising observation scale. This scale measures pain in nursing home patients with cognitive impairments, communication difficulties, or both. Among

these patients can be patients in terminal stages of illness. For the detection of delirium, the Delirium Observation Screening (DOS) scale has been developed.

Palliative sedation is the intentional induction of sleep in patients with a very short life expectancy who suffer intractable distress. The aim of palliative sedation is to provide comfort. At the end of life palliative sedatie can be an option, when standard therapy to relieve symptoms is inadequate and symptoms seems to become untreatable. It is estimate that in the Netherlands palliative sedation is used by doctors in 10% of all mortality cases per year. The indications most mentioned in palliative sedation are pain, dyspnea and delirium/terminal restlessness. The efficacy and safety of palliative sedation have been hardly described. Besides, so far it is unusual to objectify palliative sedation.

The depth of sedation can be measured with observation scales, like the Ramsay scale, or with neurofysiological monitors. The most and best studied monitor is the Bispectral Index (BIS) monitor. In palliative care the use of the BIS monitor has been described still very limited.

Commonly the assessment and management of symptoms in palliative care patients depends on the experience of nurses en doctors. So far objective methods are not or hardly used to determine the presence and seriousness of symptoms.

Study objective

Commonly the assessment and management of symptoms in palliative care patients depends on the experience of nurses en doctors. So far objective methods are not or hardly used to determine the presence and seriousness of symptoms. The main goal of the study is to validate the BIS monitor during palliative sedation. Another aim is to monitor the degree of comfort in (sedated) palliative care patients in a nursing home. For this the BIS monitor and Ramsay score are used to measure the depth of sedation, the Numeric Rating Scale (NRS) and REPOS are used to qualify pain, the DOS scale is used to determine delirium, a comfort scale asked at patients and next of kin is used as general measurement for comfort and a comfort scale asked at caregivers is used as en expert opinion.

Study design

Prospective observational pilot study

Parameters:
- Data of medical file: birth date/(age), gender, data of admission in nursing home, diagnoses/morbidity, all medication (fixed and if indicated) with doses and route of administration, every change in medication with date and time, indication for sedation, duration from sedation till pass away.

- Pain: NRS/REPOS score. Done at fixed times before and during sedation. In patients whom can express themselves verbally, the NRS is used to measure pain. The REPOS will be used at the same time with the NRS, when the NRS seems to be unreliable. The REPOS is used in verbally impaired patients. Daily caregivers give a NRS for the patients pain.
- Delirium: DOS score. Three times in 24hours at regular moments of care.
- Comfort: Numeric Rating Scale. Daily patient, next of kin and caregiver give a score from 0 (totally no comfort) to 10 (optimal comfort).
- Fysical parameters: Daily measuring respiration rate, respiration regularity (normal/Cheyne Stokes) and cardiac rate.
- Sedation: BIS scores and Ramsay score. Taking a score before sedation: at daytime during 1hour and at night time during sleep. During sedation continuing monitoring, with covered monitor. Ramsay score is done at fixed times.

Study burden and risks

This study uses non-invasive measurements for sedation, pain and delirium and BIS monitoring. The participant will be visited every day during maximal 15 minutes. During such visits assessments will be done and if necessary the BIS sensor is checked or replaced. The BIS sensor can cause local redness of the skin.

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

Patients in terminal stages of illness at palliative unit in nursing home Laurens, Antonius IJsselmonde, Rotterdam; informed consent

Exclusion criteria

no informed consent;
time too short to take a BIS score before sedation

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):	11-08-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL22500.078.08