Palliative Sedation across European settings - a prospective observational multicentre study

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• To evaluate the effect of palliative sedation on patients comfort and other symptoms in different international hospices, palliative care units and hospital ward settings.• To assess the clinical practice of palliative sedation in different...

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

Summary

ID

NL-OMON52485

Source
ToetsingOnline

Brief title
PALSED

Condition

- Other condition

Synonym
Cancer patients at the end of life with untreatable symptoms, Terminal cancer patients with refractory symptoms

Health condition

Alle patienten met een primaire diagnose van kanker

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020

Intervention

Keyword: Adult, Palliative Medicine, Palliative Sedation, Patient Comfort/Methods

Outcome measures

Primary outcome

Change in discomfort levels of patients receiving palliative sedation, measured by the health care professionals using the DS-DAT, a Discomfort Score for patients with Dementia Alzheimer Type. Measured before and twice a day during the whole procedure of palliative sedation until death. This measure has been succesfully applied in sedated patients in previous studies, for example from Radboudumc.

Secondary outcome

Depth of sedation and levels of agitation are measured with the Richmond Agitation Sedation Scale, modified version for palliative care (RASS-PALL).

Study description

Background summary

Palliative sedation is defined as the intentional lowering of consciousness of a patient in the last phase of life, to relieve patients suffering from refractory symptoms. For those symptoms all possible effective treatments, within an acceptable timeframe, are exhausted.
Several studies have been performed about palliative sedation, mostly focusing on continuous deep sedation, with the use of various measurements to monitor its effect.
Efficacy of continuous palliative sedation has been monitored by agitation/distress levels, symptom control, levels of sedation/awareness,

comfort, safety and family/caregivers satisfaction.

Study objective

• To evaluate the effect of palliative sedation on patients comfort and other symptoms in different international hospices, palliative care units and hospital ward settings.

• To assess the clinical practice of palliative sedation in different international care settings and the accompanying costs and consequences.

Study design

Prospective observational multicentre study in hospices, palliative care units and hospital ward settings in five European countries (Belgium, Germany, Italy, Spain, The Netherlands).

Study burden and risks

Since our study will be observational, following regular practice, the expected amount of extra burden due to study participation will be low.

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

* Age 18 years or above;
* Primary diagnosis at admission is advanced cancer;
* Life expectancy of the patient is limited (clinical prognosis estimation 1-2 months);
* Intractable distress caused by one or more refractory symptoms during the hospitalization can be expected or is present, according the health care team;
* Able to give informed consent, or there is a possibility of proxy informed consent.

Exclusion criteria

* When a potential participant is unable to give informed consent and there is no possibility of proxy informed consent, he/she is not eligible for participation in this study.
* When a potential participant and/or the relative is unable to speak and read in the native language of the participating country, he/she is not eligible for participation in this study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2021
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-07-2022
Application type:	Amendment
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
ClinicalTrials.gov	NCT04719702
CCMO	NL72725.091.20

Study results

Date completed: 10-06-2024

Actual enrolment: 53

Summary results

Trial ended prematurely