Effect of the use of continuous sedation until death on the patient's relatives wellbeing

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The proposed study aims to evaluate the recommendations of the guideline regarding the wellbeing of the relatives according to the following questions: 1) To what extent are the recommendations of the guideline adhered to? 2) What is the effect of...

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

Summary

ID

NL-OMON38210

Source
ToetsingOnline

Brief title
UNBIASED

Condition

- Other condition

Synonym
No specific condition

Health condition

we onderzoeken het welzijn van naasten van een patient die na de toepassing van continue sedatie is overleden; de naasten zelf hebben geen specifieke aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Continuous sedation, Relatives

Outcome measures

Primary outcome

1) Focusgroup study

It concerns a qualitative study. Therefore, there are no study parameters in the strict sense. In the focusgroups, the relatives will exchange their experiences with the care for the patient in the last phase of life. Relevant themes will be obtained from their narratives.

2) Interview study

In the interviews, the following topics will be explored:

- Patient characteristics

- Relative characteristics

- Decision-making and communication with the relative

- The use of sedation

- The patient's quality of dying

- Wellbeing of the relative

3) Questionnaire study

Primary study parameters are: satisfaction regarding the dying phase, concerns,

grief and aspects of the quality of life after the patient's death (eg physical

and mental functioning, role limitations).

Secondary outcome

1) Focusgroup study

Not applicable

2) Interview study

Not applicable

3) Questionnaire study

Secondary study parameters burned-out symptoms, sick-days

Study description

Background summary

Palliative sedation entails the use of sedating drugs to induce a state of decreased consciousness to alleviate symptoms for patients who are approaching death. Palliative sedation is used in high frequencies and its use is increasing. Lowering patients* consciousness is a far-reaching intervention that has an important impact on the relatives. Relatives consider the procedure distressing. For instance, it deprives the relatives of the possibility to communicate with the patient until death and there are often concerns about the wellbeing of the patient. These factors may affect the wellbeing and the bereavement of relatives. The KNMG guideline palliatieve sedation contains recommendations regarding the wellbeing of relatives focused on information, communication and support.

Study objective

The proposed study aims to evaluate the recommendations of the guideline regarding the wellbeing of the relatives according to the following questions:
1) To what extent are the recommendations of the guideline adhered to?
2) What is the effect of the use of palliative sedation on the wellbeing of

relatives during the sedation and after the patient's death?
3) What elements of the use of palliative sedation are associated with the wellbeing of relatives during the sedation and after the patient's death?
a) Elements relating to the recommendations in the guideline
b) Other elements of the use of sedation

Study design

The proposed study concerns three parts ('mixed methods approach'):
1. A focusgroup study
2. An interview study
3. A questionnaire study

Two focusgroups are planned with relatives of patients who received sedation prior to death. The focusgroups are a preparation for the interview study. In the second part, 30 cancer patients for whom sedation was used prior to their death will be identified, and the physician, nurse and relative who were most involved in the care for the patient will be interviewed. Because there are marked differences between countries in the frequency of sedation, this study will also be performed in the UK and Flanders. For the third part, questionnaires will be send out to 525 relatives (175 relatives of sedated patients matched with 350 relatives of non-sedated patients).
All parts of the study concern a specific type of sedation: continuous sedation until death.

Study burden and risks

In this study, no invasive physical procedures will take place. Therefore, adverse events in the strict sense cannot take place.
However, we can be stirring up a lot of difficult or unresolved issues for all respondents. Death, dying and bereavement are all sensitive and potentially upsetting topics to discuss and participation in a study involving these issues can raise difficult issues. We will draw on this to ensure that the study is sensitively handled. We will liaise with each organisation to ensure that we engage in appropriate follow up. This is likely to mean ensuring that we are available to follow up any questions or issues raised, and e.g. offer relatives the opportunity to talk to the key physician of the patient if necessary. Further, we will ensure to inform participants of more formal bereavement support which they may wish to seek following their research participation.

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 deceased patient:
- Received continuous sedation until death
- Cancer as main diagnosis
- Older than 18 years of age
- Passed away < 6 weeks;Physicians and nurses:
- Involved in decisionmaking of continuous sedation until death ;Relatives
- Concerns familymember or friend
- Fulfills relatives definition NICE guideline: was involved in the care for the patient, shared in the illness experience, and was emotionally involved with the patient before and during the sedation
- Able to speak Dutch and living in the Netherlands

Exclusion criteria

Not fulfilling the inclusion criteria

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2011
Enrollment:	625
Type:	Actual

Ethics review

Approved WMO Date:	21-01-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-04-2013
Application type:	Amendment
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	NL33327.078.10