# Depth of monitoring for palliative sedation
# - A study in the context of the Amsterdam Rotterdam sedation project.

Published: 01-09-2008
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Aim of the study is to determine which instruments for monitoring the depth of palliative sedation are most reliable, and/or adequately measure the severity of treated symptoms.

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

## Summary

### ID

NL-OMON32251

**Source**
ToetsingOnline

**Brief title**
AMROSE

### Condition

- Other condition

**Synonym**
terminally ill patients

**Health condition**

terminale patiënten met diverse ethiologieën

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** Monitoring, observation scales, Palliative sedation, Reliabity

## Outcome measures

### Primary outcome

Depth of sedation

### Secondary outcome

Interrater reliability, internal consistency of the measurement scales.

# Study description

### Background summary

The past few years there has been a vivid discussion about palliative sedation. This discussion focuses on the criteria and conditions required for palliative sedation, but also concerns the relation between palliative sedation and euthanasia.
Controversially, research points out that palliative sedation is not always carried out in the dying phase and sometimes palliative sedation is applied with the explicit aim of hastening the death of the patient. A committee appointed by the Royal Dutch Medical Association (KNMG) developed a guideline palliative sedation which was implemented in December 2005. The guideline has been established in order to promote the correct application of palliative sedation.
Until now the current practice of the palliative sedation has not yet been examined fully. It is of great importance that besides a correct indication, the degree of sedation is reached which has been considered necessary and sufficient for the desired degree of symptom suppression of the individual patient. The degree of symptom control stipulates the doses of a sedatives. The KNMG guideline however contains no clear regulations for clinical monitoring of the depth of sedation. This can lead to serious problems, such as an unintentional awakening of the patient.

### Study objective

Aim of the study is to determine which instruments for monitoring the depth of palliative sedation are most reliable, and/or adequately measure the severity of treated symptoms.

### Study design

Observational design

### Study burden and risks

The study is considered observational and will not take invasive measurements. No risks have been link to this study.

## 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

* Life expectancy less than 2 weeks.
* No treatment available or treatment is harmful.
* Patient is suffering from refractory symptoms.

### Exclusion criteria

- no informed consent

## 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): | 01-09-2008 |
| Enrollment: | 45 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 01-09-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL23542.029.08 |