Death rattle in the dying phase: is prophylactic treatment useful?

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Can administration of scopolaminebutyl from the start of the dying phase prevent death rattle during the dying phase?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47094

Source
ToetsingOnline

Brief title
Reutelen

Condition

- Other condition

Synonym
Death rattle, noisy breething

Health condition

Reutelen in stervensfase, Ademhalingsstelsel

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Death rattle, Dying phase, Noisy breething

Outcome measures

Primary outcome

The percentage of patients who develop death rattle, defined as the appearance of grade 2 or higher according to the method of Back measured at 2 successive times/time points with an interval of 4 hours.

The following degrees of rattle are distinguished:

grade 0 = no audible rattle

grade 1 = rattle only audible close to the patient

grade 2 = rattle in a quiet room clearly audible at the foot of the bed

grade 3 = rattle in a quiet room audible at a distance of 10 meters (at the door of a room)

Secondary outcome

- Time from recognition of the dying phase until death rattle

- Appearance of the adverse events micturition, dry mouth and restlessness by observations noted in the digital Care plan of the dying (formerly known as Liverpool Care Pathway)

- Quality of life during the last three days of the life of the patient, according to the caregiver, indicated by a numerical value on a scale of 0 to 10 (0 = no quality; 10 = the best quality that can be imagined)

- Quality of dying of the patient, according to the caregiver, indicated by a numerical value on a scale of 0 to 10 (0 =no quality; 10 = the best quality

that can be imagined)

- Manner of death, according to the caregiver, indicated with 15 qualitative terms.

- Moment of death, according to the caregiver, indicated with 15 qualitative terms.

- Quality of Life in the last three days of the patient according to the relatives, indicated with a numerical value on a scale of 0 to 10 (0 =no quality; 10 = the best quality that can be imagined)

- Quality of dying of the patient, indicated by the relatives, indicated with a numerical value on a scale of 0 to 10 (0 = no quality; 10 = the best quality that can be imagined)

- The way of dying, according to the relatives, indicated with 15 qualitative terms.

- Moment of death, according to the relatives, indicated with 15 qualitative terms.

- Extent of bereavement for relatives according to the Leiden Score (15)

- Experience of participating in a (double-blind, placebo-controlled) scientific research trial through a questionnaire and interviews with questions about the perception and the meaning of participating in a trial indicated by a numerical value on a scale of 1 to 4 (1 = no stress; 4 = extremely stressful)

Study description

Background summary

About half of the patients in the dying phase experience death rattle: noisy breathing caused by the presence of mucus in the upper respiratory tract. Patients may be afraid of the occurrence of/to experience death rattle by memories of the dying process/phase of loved ones. If this loved one had experienced death rattle, it could be interpreted as *choking*. For relatives of a patient the rattling noise can be unpleasant and disturbing.
They may fear that their loved one suffers from it and will choke. Creating awareness by informing the patient and relatives and helping drainage of the mucus by regularly posture changes of the bedridden patient are recommended in the Dutch guideline. If the rattle is nevertheless perceived as burdensome, administration of medication (anticholinergics) can be considered. However, there is no evidence for the effect of this medication on the death rattle. Because the medication does nothing to the existing mucus, it seems to be more rational to start with medication before the death rattle exists.

Study objective

Can administration of scopolaminebutyl from the start of the dying phase prevent death rattle during the dying phase?

Study design

double-blind randomised, placebo-controlled multicenter study

Intervention

Immediately after starting of the dying phase, and the registration of the first observations, the patient is administered the study drug: scopolamine 1 ml s.c. (= 20 mg) or placebo 1 ml s.c..
This is repeated every 6 hours. The study stops when at 2 consecutive times of measurement at an interval of 4 hours, death rattle grade 2 or more is found or when patient had died.

Study burden and risks

It is expected that there will be no serious side effects related to the use of hyoscine butylbromide during the dying phase. Hyoscine butylbromide is a well-known drug which is used regularly in the dying phase and with almost no side effects in practice.
In Anglo-Saxon countries these agents are used standard in case of death rattle during the dying phase. Early use of the medication may increase the risk of side effects. Potential side effects are related to the effect of the drug on the parasympatic system, such as tachycardia, urine retention, dry mouth. However, these symptoms may also occur as part of the dying process and may not be related with hyoscine butylbromide. Normal nursing care, such as the use of a urinary catheter and regular oral care, will be delivered . In the

elderly the risk of cognitive impairment or delirium is increased. The possible side effects will be marked in the digital version of the Care pathway for the dying when they appeared during this dying phase. Observations will be regularly done/performed (at least every 4 hours), registration will be done every 4 hours.
There is no direct benefit to the patient from/by participating in this study. This research could contribute to properly care in the dying phase by making clear whether the prophylactic use of hyoscine butylbromide is effective.
It is not clear whether participating in a placebo-controlled randomized trial might have impact on the quality of death of the patient and / or on the well-being of the relatives. This is investigated by questionnaires and interviews (secondary outcome).

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

1. Admission for care and treatment in one of the participating hospice facilities
2. It is known by the patient and his/her relatives that the admission will be up to death
3. At admission life expectancy is at least 3 days
4. At explanation of the study (shortly after admission to hospice facility) and signing of the informed consent the patient is conscious
5. Presence of a signed informed consent

Exclusion criteria

1. There are signs of a respiratory infection (upper or lower respiratory tract)
2. The patient has a tracheostomy or tracheocanula
3. The patient uses an anticholinergic or octreotide
4. At the start/At recognition of the dying phase death rattle is present at grade 1 or more, according to Back

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2017
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Hyoscinebutylbromide
Generic name:	Hyoscinebutylbromide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-11-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-12-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-06-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-06-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-04-2019
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

ID: 25998
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-002287-14-NL
CCMO	NL58109.078.16
OMON	NL-OMON25998