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

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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 death rattle. Memories of loved ones with this...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25998

Bron
NTR

Aandoening

Death rattle: noisy breathing caused by the presence of mucus in the upper respiratory tract in a dying patient.

Ondersteuning

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Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of patients who develop death rattle, as defined as the occurrence of death rattle with a severity of grade ¡Ý 2 according to the scale of Back at 2 consecutive measurements with an interval of 4 hours.

Toelichting onderzoek

Achtergrond van het onderzoek

Death rattle occurs in about half of the patients in the dying phase. Relatives often experience this as disturbing. Anticholinergics are recommended to treat death rattle, although there is no evidence for the effect of these drugs. Whereas anticholinergics do not affect existing mucus, it may be more effective when given preventively. We designed a study to test this hypothesis in patients admitted to a hospice.

The study will be conducted in four hospices in the Southwest region of the Netherlands.

Participating centers:

- Laurens Cadenza, Oosterhagen 239, 3078 CL, Rotterdam

- Hospice Calando, Vivaldilaan 2 ¡§C 4, 3247 EE Dirksland

- Hospice de Regenboog, Oudedijk 11, 3062 AB Rotterdam

- Stichting Curamus, hospice de Meander, Truffinoweg 2, 4561 NT Hulst

Doel van het onderzoek

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 death rattle. Memories of loved ones with this phenomena are often associated with ¡¡ãchoking¡¡À. For the relatives its rattling noise can be unpleasant and disturbing. They may fear that their loved one suffers from it.
Awareness and posture changes in bed are the recommended actions. If the rattle is nevertheless perceived as burdensome, drugs (anticholinergics) can be considered. However, there is no evidence for the effect of these drugs. Whereas anticholinergics do not affect existing mucus, it may be more effective when given preventively. We designed a study to test this hypothesis in patients admitted to a hospice.

Onderzoeksopzet

From the start of the dying phase every four hours observations are made by the nursing staff. They report these observations in the Care Pathway for the Dying, which will be started at the moment that the dying phase is recognized. The observations will end at death of when the primary endpoint is met. The care pathway is adapted for clinical research and includes extra observations by and questions to the nursing team.

After three months a questionnaire will be sent to the relatives.

Onderzoeksproduct en/of interventie

At the recognition of the dying phase the patient will start with scopolaminebutyl 20 mg(=1 ml) or placebo (=1 ml NaCl 0.9%) four times a day subcutaneously. Treatment will be continued until death or until the occurrence of death rattle with a severity of grade ¡Ý 2 according to the scale of Back at 2 consecutive measurements with an interval of 4 hours. Standard care as provided in the hospices will be continued.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Admission in one of the participating hospice facilities, 2. Patient and his/her relatives are aware that the inclusion will be up to death, 3. Life expectancy at admission of at least 3 days, 4. no signs of disturbed consciousness at the moment of asking informed consent (shortly after admission to hospice facility) and signing of the informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Signs of active respiratory infection (upper or lower respiratory tract), 2. Tracheostomy or tracheal cannula in situ, 3. Use of an anticholinergic drug or octreotide, 4. At entering the dying phase death rattle ¡Ý grade 1 according to the scale of Back

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	24-04-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47094
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6264
NTR-old	NTR6438
CCMO	NL58109.078.16
OMON	NL-OMON47094

Resultaten

Samenvatting resultaten
In 2020 the results will be published.