Identification of Patients with COPD with a Poor Prognosis and Implementation of Proactive Palliative Care

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20335

Bron
NTR

Verkorte titel
PROLONG

Aandoening

COPD, palliative care, quality of life, prognosis, indicators start palliative care, readmission, mortality
COPD, palliatieve zorg, kwaliteit van leven, prognose, indicatoren start palliatieve zorg, heropname, sterfte

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure of the indicator study is:
- Length of time from the moment that a patient hospitalized for AECOPD meets two or more criteria of the set of indicators until death for any cause.
The primary outcome measure of the intervention study is:
- Quality of life of the patient (SGRQ)

Toelichting onderzoek

Achtergrond van het onderzoek

Proactive palliative care is not very common for patients with Chronic Obstructive Pulmonary Disease (COPD). Important barriers in the provision of proactive palliative care for patients with COPD are: the identification of patients who can benefit from proactive care and the organization of proactive palliative care. Based on recent literature a set of indicators is developed to identify patients hospitalized for acute exacerbation COPD (AECOPD) who are at risk for post-discharge mortality. Once identified a multi disciplinary approach to palliative care with access to a specialized palliative care team will be offered. The study is divided into an indicator study and an intervention study. We expect the set of indicators to be indicative of predicting readmission within 8 weeks and/or death within 1 year for patients hospitalized for AECOPD. We also expect that proactive palliative care for patients with COPD will: increase the quality of life of these patients, decrease the level of overburdening of their caregivers, decrease the number and length of acute hospital admissions and ICU admissions, prolong survival, and decrease the amount of patients that die in the ICU.

Doel van het onderzoek

The study consists of an indicator study and an intervention study.

1. Indicator study

We expect that the set of indicators will have discriminative power to predict readmission within 8 weeks and/or death within 1 year for patients hospitalized for AECOPD .

2. Intervention study

We expect that proactive palliative care for patients with COPD will: increase the quality of life of these patients, decrease the level of overburdening of their caretakers, decrease the number and length of acute hospital admissions, prolong survival, and decrease the amount of patients that die in the ICU.

Onderzoeksopzet

The patients and their main caregiver will be followed at baseline (during hospital admission), and thereafter every 3 month until the end of the trial at 18 months by administering questionnaires (for patients: SGRQ, McGill, HADS and illness understanding; for main caregivers: EDIZ, HADS and illness understanding). In addition, retrospectively the researchers extract data from the medical records of the patients at the end of the trial over the complete trial period. They will look for date, number and length of unexpected hospital admissions, date, number and length of unexpected ICU admissions, the choices of Advance Care Planning (ACP), place of death and length of survival.

Onderzoeksproduct en/of interventie

The investigational product is a behavioral intervention. In the intervention hospitals, members of the specialized palliative care teams will receive training in implementation of palliative care for patients with COPD. The training will be given by palliative care professionals of the UMC St. Radboud in Nijmegen and will take place in the three month before start of the controlled trial. It consists of two consecutive meetings of each three hours. The following topics will be discussed:

· Discussion of end of life aspects with patient and family;

· Creating a patient-tailored supportive care plan;

· Learning to anticipate on illness- and dying scenarios;

· Transfer of care to lung specialist and general practitioner (GP);

· Performing the supportive care plan in cooperation with the lung specialist.
During the controlled trial patients in the intervention hospitals who are assigned for palliative care will meet with a member of the palliative care team within 1 week after enrolment and at least monthly thereafter in the outpatients setting until the end of the trial or death. The main caregiver of the patient will be asked to be present at those meetings. Guidelines for the palliative care meetings in the ambulatory setting are adapted from the general guidelines palliative care in the Netherlands.

Contactpersonen

Publiek

UMC St Radboud
Huispost 630 Anaesthesiologie / Palliatieve Zorg
Postbus 9101

Yvonne Engels
Kamer: route 485
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3616583

Wetenschappelijk

UMC St Radboud
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Kamer: route 485
Nijmegen 6500 HB
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+31 (0)24 3616583

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- All patients with an acute exacerbation COPD (AECOPD) admitted to the hospital, and

- Aged 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Not speaking the dutch language, or

- Severe cognitive disorders, or

- At moment of inclusion in treatment with a specialized palliative care team.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2013
Aantal proefpersonen:	174
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3869

Register	ID
NTR-old	NTR4037
Ander register	CMO registration number : 2012/260
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A