A prospective, randomised controlled multi-centre trial comparing in-hospital treatment and early assisted discharge for exacerbations of Chronic Obstructive Pulmonary Disease (COPD).

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Early assisted discharge for exacerbations of Chronic Obstructive Pulmonary Disease (COPD) is an effective and cost-effective treatmentmodel in the Dutch health care system.

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

Samenvatting

ID

NL-OMON23731

Bron
NTR

Verkorte titel
GO AHEAD

Aandoening

Chronic Obstructive Pulmonary Disease (COPD), exacerbation treatment, early assisted discharge, cost-effectiveness. patient preference.

Ondersteuning

Primaire sponsor: University Maastricht (UM), CAPHRI institute
iMTA, Erasmus MC Rotterdam
Overige ondersteuning: ZonMw Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is the CCQ score measured on day 7, representing changes in health condition.

Toelichting onderzoek

Achtergrond van het onderzoek

Exacerbations of Chronic Obstructive Pulmonary Disease cause many hospitalisations, leading to high health care expenses. Because of increasinng prevalence numbers the burden of COPD in the future will only increase.

There is a need for new treatmentmodels of which early assisted discharge is an example. Early assisted discharge schemes are not new, but have not been applied in the Dutch health care system. Also the cost-effectiveness of these schemes has not been proven yet.

In this randomised controlled trial patients that are hospitalised for an exacerabtion COPD are early assisted discharged on the fourth day. At home they receive care until the seventh day, from a nurse from the home care organisation. This nurse monitors the recovery of the patient, and if neccesary contacts the hopsital to consult the pulmonologist. At one month and 3 months after discharge from the program the patient visits the outpatient clinic for follow ups. At three month the study ends for the patient. Patients and their direct caregivers are asked to fill in questionnaires on time points day 1, day 3, day 7 and 3 months.

The trial is conducted in three hospitals, namely Catharina-ziekenhuis Eindhoven, Maxima Medisch Centrum Eindhoven/Veldhoven and Atrium Medisch Centrum Heerlen. In total 235 patients will be included. The cost-effectiveness part of the study will be perfomed by the IMTA institute of the ErasmusMC.

Doel van het onderzoek

Early assisted discharge for exacerbations of Chronic Obstructive Pulmonary Disease (COPD) is an effective and cost-effective treatmentmodel in the Dutch health care system.

Onderzoeksopzet

Day 1, 3 and 7 of treatment phase.

Follow up at 1 month and 3 months.

Onderzoeksproduct en/of interventie

Intervention group will be early assisted discharged home on the fourth day of hospitalisation. They will receive the same medical treatment as the control group, but in their own environment.

The intervention group receives guidance of a nurse of the home care organisation until the seventh treatment day. The nurse not onlyl assists with daily activities, but also more disease related activities like breathing techniques or disease management.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 40 and older;

2. Competent;

3. COPD defined as minimally GOLD I and 10 PY;

4. Moderate to severe exacerbation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Major uncontrolled co-morbidity;

2. Mental disability;

3. Active alcoholism and/or drug abuse;

4. Inability to understand the program;

5. Living outside the region of care of the home care organisation;

6. Indication for ICU admission or NIPPV;

7. Insufficient direct caregiver.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-11-2007
Aantal proefpersonen:	235

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2007
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	NL1095
NTR-old	NTR1129
Ander register	METC. nr. : M07-1755
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A