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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23731

Source
NTR

Brief title
GO AHEAD

Health condition

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

Sponsors and support

Primary sponsor: University Maastricht (UM), CAPHRI institute
iMTA, Erasmus MC Rotterdam
Source(s) of monetary or material Support: ZonMw Nederland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes are:

1. Number of treatment failures;

2. Health care consumption/health care costs;

3. 3-month clinical control (CCQ EQ-5D);

4. 3-month re-admission rate;

5. 3 month mortality rate;

6. Patient and direct caregiver's satisfaction
also a DCE will be performed to study which treatment characteristics influence patients' and cargivers' preferences for home or hospital treatment.

Study description

Background summary

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.

Study objective

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

Study design

Day 1, 3 and 7 of treatment phase.

Follow up at 1 month and 3 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 40 and older;

2. Competent;

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

4. Moderate to severe exacerbation.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2007
Enrollment:	235
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-11-2007
Application type:	First submission

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
NTR-new	NL1095
NTR-old	NTR1129
Other	METC. nr. : M07-1755
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A