# Early pulmonary rehabilitation after hospitalisation for acute exacerbation COPD.

Published: 01-06-2006
Last updated: 14-05-2024

Evaluating the effects of early pulmonary rehabilitation on exercise capacity, quality of life and readmission.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bronchial disorders (excl neoplasms) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30057

**Source**
ToetsingOnline

**Brief title**
Rehabilitation for exacerbation COPD.

### Condition

- Bronchial disorders (excl neoplasms)

**Synonym**
exacerbatie COPD, relapse of infection of the lower airways

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken
**Source(s) of monetary or material Support:** maatschap longziekten

## Intervention

**Keyword:** acute exacerbation, COPD, rehabilitation

## Outcome measures

### Primary outcome

exercise tolerance in meters.

### Secondary outcome

exacerbations and (re)admissions rate.

quality of life.

# Study description

### Background summary

Hospital admissions because of exacerbation COPD is a burden. Despite optimal therapy during admission, rthe ecovery time after discharge lasts long. A previous trial has shown that 25 % of the patients is not recovered at all, three months after discharge from the hospital, measured in lungfunction. Recovery of the quality of life is lasting longer, even if an exacerbation does not occur. Admission because of exacerbation COPD increases the risk of readmission. Interventions leading to fast recovery and improving symptoms after a hospital admission, would not decrease only readmissions, but would increase also quality of life of the COPD patient in daily life. Pulmonary rehabilitation is a multidisciplinary treatment, whereby medical and psychosocial interventions including training, education and nutrition are used. Pulmonary rehabilitation by stable COPD patients is seemed to be regular care and cost-effective. However, the effect of early pulmonary rehabilitation by acute exacerbation patients in the recovery period is not investigated properly. The expectancy is that early rehabilitation after admission because of exacerbation COPD is safe and will profound statistically and clinically improvement in exercise capacity, quality of life and a decrease of hospital readmissions.

### Study objective

Evaluating the effects of early pulmonary rehabilitation on exercise capacity, quality of life and readmission.

## Study design

Hundred patients with an acute exacerbation of COPD admitted to the regular pulmonology department via the emergency room are recruited, after they have given written informed consent. Inclusion criteria are an age > 40 years or <= 80 years, at least 10 packyears of smoking history and COPD at least GOLD II. Each form of physical therapy is accepted outside pulmonary rehabilitation. Exclusion criteria include participation in a pulmonary rehabilitation program in the preceding year, comorbidity that can limit exercise training (for example: invalidating ischaemic heart disease, RA, malignancy and lung embolus), intolerance to prednisolon, history of asthma, non-compliance, findings on chest radiography other than fitting with signs of COPD and a prior randomisation. During admission patients are receiving standard exacerbation COPD treatment consisting of O2, Combivent inhalation, antibiotics and prednison. Exercise capacity is measured by a 6 minute walk test performed before randomisation and discharge from the hospital as well as a spirometry. These measurements will be repeated after discharge from hospital at 3 months. Quality of life is evaluated by the following questionnaires at discharge: St. George respiratory questionnaire (SGRQ), SF-36-scores (short form health survey) and CCQ. Before discharge patients are randomised with a computer minimisation program for pulmonary rehabilitation or usual care with special attendance to age (< 70 years or >= 70 years), sex, length of hospital admission (< 7 days or >= 7 days ), six minute walk test distance at discharge (< 100 meters >= 100 meters ) and predicted forced expiratory volume in one second (FEV1< or >= FEV1). Pulmonary rehabilitation will take place within ten days after discharge and shall be given by a multidisciplinary team (pulmonologist, respiratory nurse, physical therapist, dietician and a social worker). The program will last 2 hours weekly; 1 hour exercise training and one hour education during 8 weeks. All patients are followed up after discharge at 3 and 6 months.The questionnaires will be repeated at 3 and 6 months. Readmission rate will be also evaluated in this period.

## Intervention

Participate to early pulmonary rehabilitation during 8 weeks for 2 hours weekly.

## Study burden and risks

Patients have to perform the walk test twice, have to blow a spirometry twice and have to fill in the three quality of life questionnaires for 3 times during hospital admission and after discharge. Patients have to participate also to the weekly 2 hour lasting pulmonary rehabilitation program. Patients will receive a taxi-pass for these visits. There are no direct adverse effects due to the rehabilitation program. Patients in the *regular care* group will not be guided by the multidisciplinary rehabilitation team. Exercise and physical

therapy outside pulmonary rehabilitation is tolerated. The expected benefits are a better exercise tolerance, less exacerbations, a lower re-admission rate and a better quality of life. Patients will also be seen more often after discharge. Two appointments will be made after discharge from the hospital. Questions will be answered during these visits.

## Contacts

**Public**
Isala Klinieken

Groot Wezenland 20
8011 J W Zwolle
Nederland
**Scientific**
Isala Klinieken

Groot Wezenland 20
8011 J W Zwolle
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

age between 40 and 80 years
at least COPD GOLD II
at least 10 packyears of smoking history

physical therapy outside pulmonary rehabilitation

### Exclusion criteria

pulmonary rehabilitation in previous year
comorbidity limiting rehabilitation
intolerance to prednison
non-compliance
asthma in history
prior randomisation in trial
radiological findings not fitting with COPD

## Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-02-2007 |
| Enrollment: | 100 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Registration: | No |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 29-08-2006 |

| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Isala Klinieken (Zwolle) |

# 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 |
|---|---|
| CCMO | NL11494.075.06 |