# A randomised controlled trial for the effect of preoperative physiotherapy in patients with an increased risk for the development of postoperative pulmonary complications after open-heart surgery.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON29003

**Source**
NTR

**Brief title**
PORT

**Health condition**

Coronay artery bypass graft (CABG) surgery

### Sponsors and support

**Primary sponsor:** ZonMW (projectnr. 1310.0004)
**Source(s) of monetary or material Support:** UMC Utrecht

### Intervention

### Outcome measures

**Primary outcome**

Postoperative pulmonary complications (PPCs) are defined as “any pulmonary abnormality occurring in the postoperative period that produces identifiable diseases or dysfunctions that are clinically significant and adversely affect clinical developments” (Brooks-Brunn, 1995). In this study, PPCs are explicitly classified and treated according to the criteria of Kroenke et al. (1992).

### Secondary outcome

Length of hospital stay.

## Study description

### Background summary

Open-heart surgery implies both long-time general anaesthesia and comprehensive intrathoracic manipulations. This has negative effects on the respiratory system and especially on the pulmonary functions.
One of the main effects of this interference is a significant increase of developing of postoperative pulmonary complications (PPCs). PPCs are the main cause of postoperative mortality and morbidity. Depending on the definition the incidence of PPC after open-heart surgery varies between 7.5% (pneumonia) and 80% (atelectasis). Prevention of PPC is a primary aim of the care, part of which is the clinical physiotherapy.
For the prevention of PPC the physiotherapist has different interventions at his or her disposal. However, scientific studies show that physiotherapeutic interventions have only limited effects when they are only post-operatively executed on OHS patients that already developed a PPC. This is in contrast to preventive, pre-operative, physiotherapeutic interventions, that seem to have a protective effect in relation to the prevention of PPCs.
In practice, the employment of physiotherapeutic interventions before an OHS is more the exception than the rule, however. This study focused on this situation und investigated the effect of preoperative physiotherapy on the prevention of PPC after OHS.

### Study objective

Preoperative physiotherapy decreased the incidence of postoperative pulmonary complications (PPCs) after open heart surgery on patients with an increased risk of developing PPCs.

### Study design

N/A

### Intervention

The pre-operative physiotherapy consists of a combination of respiratory exercises involving the costo-diaphragm breathing technique, training of the inspiratory muscles for strength and endurance, and teaching a good technique for coughing and “forced expiration techniques”. The method, involving a progressive training course, is initiated 4 weeks before the operation.
The training period and progress of the training are sufficient to improve the strength and endurance of the respiratory musculature (also: accessory respiratory muscles). Neuromuscular changes are especially important to increase the efficiency of breathing by the OHS patient. Exercise periods lasting 20 minutes are conducted once per day seven days each week.
The therapy is continued by the patient at home, once per week under the supervision of a physiotherapist and 6 times per week alone. During the supervised training at the beginning and at the end of the period of application, the heart rate and the blood pressure are measured to determine the cardiovascular stress.
In addition the patient keeps a diary, in which he notes the number of exercise sessions completed per week, the duration of each session, and the subjectively experienced stress. In the diary, space is provided for notes regarding physical complaints and problems that occurred before, during or after the exercises.

## Contacts

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## Eligibility criteria

## Inclusion criteria

1. All patients who undergo voluntary CABG surgery and have an increased risk of developing a PPC are included in the study.

2. High risk for the development of PPCs is determined by using the risk model (Hulzebos et al.) during the preoperative consultation with the anaesthesiologist (6-8 weeks before the operation) (5).

3. Additional criteria for inclusion in the study are that patients understand Dutch language, and are able to read, are capable of passing a spirometer test and a determination of the mouth pressure, and are prepared to sign a contract of informed consent.

## Exclusion criteria

Criteria excluding patients from the experiment include cerebrovascular illnesses;

1. immunosuppressive treatment < 30 days before the operation (chemotherapy or radiotherapy);

2. neuromuscular illnesses (among others Guillein Barré, muscular dystrophy, myasthenia gravis);

3. a previous lung operation;

4. cardiovascular instability;

5. the presence of aneurisms;

6. lung physiotherapy < 8 weeks before the operation;

7. and postoperative cardiac and/or complications involving the central nervous system.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Factorial |
| Allocation: | Randomized controlled trial |

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| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 24-06-2002 |
| Enrollment: | 600 |
| Type: | Actual |

## Ethics review

Positive opinion

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| Date: | 08-09-2005 |
| 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 | NL237 |
| NTR-old | NTR275 |
| Other | : ZonMw nr. 1310.0004 |
| ISRCTN | ISRCTN17691887 |

# Study results

**Summary results**

Hulzebos HJ, Van Meeteren NLU, de Bie RA, Dagnelle PC, Helders PJM, Prediction of postoperative pulmonary outcome by preoperative risk factors in coronary artery bypass graft patients. Physical Therapy 2003;83:8-16.