

# 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

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<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

ZonMw reference 1310.0004

## **Study information**

### **Scientific Title**

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

### **Acronym**

PORT

### **Study objectives**

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

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the local medical ethics committee

### **Study design**

Multicentre, randomised, single blind, active controlled, factorial group trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Postoperative pulmonary complications

### **Interventions**

The preoperative 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 four 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 six 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.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Specified

### **Primary outcome measure**

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.

### **Secondary outcome measures**

Length of hospital stay.

### **Overall study start date**

24/06/2002

### **Completion date**

01/10/2006

## **Eligibility**

### **Key inclusion criteria**

1. Undergo voluntary coronary artery bypass graft (CABG) surgery
2. Have an increased risk of developing a PPC. High risk for the development of PPCs is determined by using the risk model during the preoperative consultation with the anaesthesiologist (6 - 8 weeks before the operation)
3. Understand Dutch language
4. Able to read
5. Capable of passing a spirometer test and a determination of the mouth pressure
6. Prepared to sign a contract of informed consent

### **Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

600

**Key exclusion criteria**

1. Cerebrovascular illnesses
2. Immunosuppressive treatment less than 30 days before the operation (chemotherapy or radiotherapy)
3. Neuromuscular illnesses (among others Guillein Barre, muscular dystrophy, myasthenia gravis)
4. A previous lung operation
5. Cardiovascular instability
6. The presence of aneurisms
7. Lung physiotherapy less than eight weeks before the operation
8. Postoperative cardiac and/or complications involving the central nervous system

**Date of first enrolment**

24/06/2002

**Date of final enrolment**

01/10/2006

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Utrecht

Amsterdam

Netherlands

3508 GA

**Sponsor information****Organisation**

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.zonmw.nl>

**ROR**

<https://ror.org/01yaj9a77>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University Medical Center Utrecht (UMCU) (The Netherlands)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/10/2006		Yes	No
<a href="#">Results article</a>		10/11/2007		Yes	No
<a href="#">Results article</a>	Secondary analysis	16/04/2016	28/10/2022	Yes	No