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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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 28/10/2022	**Condition category** Surgery	

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)

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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?
Results article		18/10/2006		Yes	No
Results article		10/11/2007		Yes	No
Results article	Secondary analysis	16/04/2016	28/10/2022	Yes	No