Study Protocol

Unique Protocol ID: ETLR13037

Brief Title: Comparison of Two Modes of Respiratory Physiotherapy in Cardio-thoracic Surgical Patients

Official Title: Comparison of Two Modes of Respiratory Physiotherapy in Cardio-thoracic Surgical Patients

Study Start: September 2013 Primary Completion: March 2016

Study Completion: December 2018 [Anticipated]

Sponsor/Collaborators

Sponsor: Tampere University Hospital Responsible Party: Sponsor

Collaborators: Tampere University of Technology

Oversight

Review Board: No, local researchers do the review

Data Monitoring: No

Plan to share data: Depending on the local data regulations

Oversight Authorities:

Approval Status: Approved Approval Number: ETLR13037

Board Name: Tampere University Hospital Ethics Committee Board Affiliation: Kirsi Kohonen
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Finland: Ethics Committee

Study Description

Brief Summary: Two forms of pre and postoperative physiotherapy are compared in three cohorts of patients undergoing cardio-thoracic surgery: Minor thoracic surgery (biopsy), major thoracic surgery (lobectomy etc, open or VATS) and cardiac surgery

Detailed Description: Inspiratory force calibrated training is applied in a controlled randomized trial

Conditions

Conditions: Respiratory Function Pulmonary Complications

Physiotherapy

Study Design

Study Type: Interventional Primary Purpose: Supportive Care

Study Phase: completed
Intervention Model: Single Group Assignment

Number of Arms: 2
Masking: Open Label

Allocation: Randomized Endpoint Classification: Safety/Efficacy Study

Enrollment: 120 [Anticipated]

Arms and Interventions

Experimental: Physiotherapy w/Inspiratory force training Chest Physiotherapy Chest Physiotherapy w/Inspiratory force training

Arms	Assigned Interventions
Active Comparator: Physiotherapy w/Positive end expiratory pressure training Chest Physiotherapy w/Positive end expiratory pressure training	Chest Physiotherapy

Outcome Measures Primary Outcome Measure:

1. Change in lung function
[Time Frame: Preop + 1-3 postoperative days] [Safety Issue: No]

2. Change in respiratory effort

[Time Frame: Preop + 1-3 postoperative days] [Safety Issue: No]

3. Change in peripheral oxygen saturation
[Time Frame: Preop + 1-3 postoperative days] [Safety Issue: No]

Secondary Outcome Measure:

4. Change in lung atelectasis
[Time Frame: Preop + 1-3 postoperative days] [Safety Issue: No]

5. Change in postoperative complications
[Time Frame: Preop + 1-3 postoperative days] [Safety Issue: No]

Eligibility

Minimum Age: 16 Years
Maximum Age: 99 Years Gender: Both (Male, female)

Inclusion Criteria:

• cardiothoracic operation, informed consent

Exclusion Criteria:

• reduced co-operation (such as psychiatric diagnosis), severe neurologic disease affecting respiratory function, alcohol or drug abuse at hospital entry, tuberculosis or other contagious lung infection, severe

respiratory insufficiency SpO2 < 90 or blood pO2 <8 or rep.rate > 25/min at rest or supplementary oxygen required at home, cardiac pacemaker.

Contacts/Locations

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