Preliminary effectiveness and feasibility of two pre-operative Inspiratory Muscle Training (IMT) interventions in patients undergoing oesophageal resection

Published: 20-07-2009
Last updated: 06-05-2024

Main objective is to examine the preliminary effectiveness of preoperative IMT high-intensity in patients undergoing oesophagus resection on postoperative pulmonary complications, inspiratory muscle strength/endurance and IC stay compared to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33515

Source
ToetsingOnline

Brief title
Effectiveness and feasiblity of preoperative IMT

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Respiratory tract infections
- Gastrointestinal therapeutic procedures

Synonym
Pulmonary infections after oesophagal resection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Effectiveness, Inspiratory, Muscle, Training

Outcome measures

Primary outcome

•% pulmonary postoperative complications (i.e. atelectases, pneumonia,

pulmonary oedema and respiratory failure, see appendix I)

Secondary outcome

- Maximal inspiratory muscle strength and endurance (Pi max and Pm-peak/Pimax)

- % compliance and % adherence rate

- Dyspnoea and muscle fatigue (Borg)

- Duration of mechanical ventialtion

- Number of re-intubations

- Diaphragm function

- Lung volumes/oxygen uptake, gas exchange

- Self-efficacy (ALCOS)

- Anxiety (STAY-DI)

- Pain (Visual Analogue Scale), dyspnea an muscle fatigue (Borg)

- Complications/adverse events

Study description

Background summary

Early post-operative pulmonary complications (PPC), including pulmonary edema, atelectasis and pneumonia frequently occur after major thoracic surgery (esophagectomy, pneumonectomy, CABG), especially in high-risk patients (high age, diabetes, smoking, co-morbidity). The rate of postoperative pulmonary complications after thoracic surgery such as CABG varies between 20-95% and for oesophageal resection between 8 to 45 %. PPCs are strongly associated with prolonged intubations and stay on ICU and general ward, and can have a high impact on costs of treatment.
Preoperative inspiratory muscle training (IMT) may be beneficial to prevent PPCs. The aim of preoperative IMT in general is to improve respiratory function by improving inspiratory muscle strength and/or endurance. The beneficial effect of preoperative inspiratory muscle endurance training (IMT-endurance) in high-risk patients undergoing CABG surgery has recently been reported and consisted of a reduction of postoperative pulmonary complications of almost 50% after a two to four week respiratory training program, and an improvement in inspiratory muscle strength of 14.5 mm H20 (=18%). In this study, IMT was applied as endurance training of the respiratory muscles. However, another modality of IMT, i.e. high-intensity IMT, aimed at improving lung function by increasing respiratory muscle strength, has been shown to be beneficial in healthy adults, in patients with COPD and in chronic heart failure. In these studies, inspiratory muscle strength increased with 41%, 29% and 31%, respectively. IMT high -intensity is not used as a preoperative intervention yet, and its effects on postoperative pulmonary complications are not clear. However, the effect sizes of IMT high-intensity with respect to inspiratory muscle strength that have been reported so far indicate that it may be more beneficial than IMT endurance

Study objective

Main objective is to examine the preliminary effectiveness of preoperative IMT high-intensity in patients undergoing oesophagus resection on postoperative pulmonary complications, inspiratory muscle strength/endurance and IC stay compared to preoperative IMT -endurance. Secondary objective is to examine the feasibility (i.e. patient satisfaction, compliance) of preoperative IMT high-intensity in patients undergoing thoracic surgery (for oesophagus resection) compared to preoperative IMT -endurance

What are the effects of IMT high intensity on postoperative complications, inspiratory muscle strength/endurance, stay on IC and general ward, compliance and patient satisfaction, self-efficacy and anxiety compared to IMT- endurance?

Study design

The present pilot study is designed as a randomised, controlled trial with two arms.
The RCT will include 30 patients per arm and will be performed with a blinded

observer. The setting for the study will be the Centre for Rehabilitation of the University Medical Centre Groningen, location Groningen

Study arms, (pilot) RCT
-IMT - high intensity group - patients in this group will receive an inspiratory muscle training programme based on a high intensity protocol.
-IMT - endurance group - patients in this group will receive an inspiratory muscle training programme based on an endurance protocol.

Measures will be performed before (T0) and after the IMT (T1, pre-operatief), and during the post-operative period (T2, day 1 to day of discharge)

Intervention

Both IMT interventions will consist of preoperative, individually tailored breathing exercises during 3-6 weeks prior to surgery (i.e. the waiting period for oesophageal resection). The IMT will be given with a Threshold IMT device. Threshold IMT devices provide a constant, sustained pressure challenge throughout the entire inspiration that is independent of airflow. When inspiring through a pressure threshold device, the individual must generate a minimum inspiratory muscle force to overcome a threshold load by generating an inspiratory pressure sufficient to open the spring-loaded valve, and must sustain this pressure level throughout the inspiration. Before starting the training Maximal Inspiratory Pressure (Pi-max) will be determined.
1)IMT high intensity: This training will be provided as a preoperative interval-based high-intensity inspiratory muscle training programme. The training includes 6 cycles of 6 inspiratory breathing manoeuvres on an inspiratory threshold loading device. Rest times between the cylci are progressively reduced from 60 seconds to 45, 30, 15 10 and 5 seconds. The training starts at 60% of the Maximal Inspiratory Pressure (MIP) and will be increased to 80% in three sessions. Then the load will be increaesd to maximal load if possible. If patients are able to keep the valve easily open during the entire session, the load will be increased with 5%. The MIP will be measured each week to adjust the training intensity to the current level of performance.The training starts six to three weeks before surgery and will be performed 3 times a week.
2)IMT endurance. This training will be provided as a preoperative inspiratory muscle endurance training programme. The training includes 20 minutes breathing on an inspiratory threshold loading device. The training starts at 30% of the Maximal Inspiratory Pressure (MIP) and will be increased with 5% if a Borg score of < 5 is achieved. The training starts six to three weeks before surgery and will be performed to 7 times a week.
Both training programmes will be performed 3 times a week under supervision of a physical therapist in the UMCG. Because IMT endurance has been shown to be feasible and safe, the other sessions can be performed at home.
For the present study both IMT interventions will be delivered with self-efficacy enhancing techniques. Self-management and/or self-efficacy

enhancing programmes are reported to have beneficial effects on several health-related outcome measures and quality of life in chronic diseases on exercise adherence and adoption, and anxiety. The self-management training program includes goal setting, monitoring, decision making, action, and feedback. In addition, self-efficacy enhancing techniques such as mastery experiences, verbal persuasion, and vicarious experiences will be included during the IMT interventions.

Study burden and risks

To our knowledge, there are no specific risks associated with this study. The physical burden for the patients consists of measurements of PI max, lung volumina (spirometry), and diaphragm function (EMG). In addition, patients have to fill in four questionnaires which will take approximately 30 minutes to complete.
Patients have to perform a preoperative inspiratory training programme for 4-6 weeks, 3 times a week, under supervision of a PT in the hospital. Patients may perceive the training or the travelling as inconvenient, otherwise they may perceive the supervision and/or the intervention as an extra moment of exertion of control during a waiting period for a cancer-related surgery which usually is a period of high anxiety and insecurity. The perception of exertion control may reduce feeling of anxiety and increase patients* level of self-efficacy. Furthermore, the benefits for the patients may consist of a reduction of postoperative pulmonary complications and a shorter IC stay. These benefits are expected to be equally large in both intervention groups. The investigators do not expect any undesirable effects of the training program. The subjects might experience muscle sore following training that will disappear after a couple of days.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients selected for oesophagal resection due to cancer

Exclusion criteria

•Neuromuscular disorders that might impede the performance and effects of muscle training
•Paresis of facial nerve that might impair the use of the IMT-device
•Inability of travelling independently to the rehabilitation centre
•Cognitive disorder or emotional instability that might impede the participation in the rehabilitation program
•Participation in any other clinical trial that measures quality of life or physical functions (exception: follow-up evaluation of clinical trials)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26588.042.09