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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21728

Source
NTR

Health condition

oesophageal resection, Inspiratory Muscle Training, pulmonary complications

Sponsors and support

Primary sponsor: Universitair Medical Center Groningen
Source(s) of monetary or material Support: UMCG doelmatigeheidsfonds

Intervention

Outcome measures

Primary outcome

Postoperative pulmonary complications.

Secondary outcome

1. Maximal inspiratory muscle strength and endurance;

2. Compliance rate;

3. Time to detubation;

4. Number of re-intubations;

5. Duration of IC stay/general ward;

6. Diaphragm function;

7. Lungvolumes;

8. Self-efficacy, anxiety and patient satisfaction.

Study description

Background summary

Objective:

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.

Study design:

Randomized Controlled Trial, with blinded observers.

Study population:

Patients undergoing oesophagus resection, age 18-85 yr.

Intervention:

Both IMT interventions will consist of preoperative, individually tailored breathing exercises during 3 – 6 weeks prior to surgery. The IMT will be given with a Treshold IMT device, which provide a constant, sustained pressure challenge throughout the entire inspiration that is independent of airflow. The IMT endurance training starts at a resistance of 30% of MIP and the patient breathes through the device during 20 minutes. The resistance will be increased with 5%, if the perceived exertion scored on the Borg scale (0-10) is less than 5. The IMT high intensity training starts at 60 % of MIP and contains 6 cycles of 6 inspiratory breathing manoeuvres. The load will be increased to maximal load.

Main study parameters/endpoints:

Postoperative pulmonary complications, maximal inspiratory muscle strength and endurance, compliance rate, duration of IC stay/general ward, lself-efficacy, anxiety and patient satisfaction.

Study objective

Both modalities of IMT will reduce postoperative pulmonary complications and IC stay.

Study design

T1= Pre pIMT;

T2 = Post pIMT;

T3 = Post surgery, discharge.

Intervention

1. The IMT endurance training starts at a resistance of 30% of MIP and the patient breathes through the device during 20 minutes. The resistance will be increased with 5%, if the perceived exertion scored on the Borg scale (0-10) is less than 5;

2. The IMT high intensity training starts at 60 % of MIP and contains 6 cycles of 6 inspiratory breathing manoeuvres. The load will be increased to maximal load.

Both interventies will be provided between 1 and 6 weeks preoperatively.

Contacts

Public
Postbus 30.002
E. Weert, van
Centre for Rehabilitation
University Medical Centre Groningen
Dilgtweg 5
Haren 9750 ND
The Netherlands
+31 (0)50 5338614
Scientific
Postbus 30.002
E. Weert, van
Centre for Rehabilitation
University Medical Centre Groningen
Dilgtweg 5
Haren 9750 ND
The Netherlands
+31 (0)50 5338614

Eligibility criteria

Inclusion criteria

1. Age over 18;

2. Diagnosis of oesophageal cancer and selected for oesophageal resection according to the judgement of the surgeon;

3. Knowledge of the Dutch language.

Exclusion criteria

1. Neuromuscular disorders that might impede the performance and effects of muscle training;

2. Paresis of facial nerve that might impair the use of the IMT-device;

3. Inability to travel independently to the rehabilitation centre;

4. Unstable asthma;

5. History of spontaneous pneumothorax;

6. Cognitive disorder that might impede the participation in the rehabilitation program (for example: subjects who are unable to be instructed, to think in three dimensions, to fill in questionnaires);

7. Emotional instability that is expected to possibly impede the participation in the rehabilitation program (for example getting divorced at the moment, death of a loved one);

8. 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-05-2011
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	NL2781
NTR-old	NTR2921
Other	METC UMCG : ID/ 26588
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Adrichem EJ van, Meulenbroek RL, Dijkstra PU, Plukker JTM, Groen H, Weert E van. (18-22 september) Barcelona (Spanje). Variation in measurement results of maximal inspiratory muscle strength testing. European Respiratory Society Congress