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

Gepubliceerd: 27-05-2011 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21728

Bron
NTR

Aandoening

oesophageal resection, Inspiratory Muscle Training, pulmonary complications

Ondersteuning

Primaire sponsor: Universitair Medical Center Groningen
Overige ondersteuning: UMCG doelmatigeheidsfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative pulmonary complications.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

T1= Pre pIMT;

T2 = Post pIMT;

T3 = Post surgery, discharge.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2781
NTR-old	NTR2921
Ander register	METC UMCG : ID/ 26588
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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