Multimodal prehabilitation in NSCLC patients undergoing surgery

No registrations found.

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

Summary

ID

NL-OMON21254

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Non-small cell lung cancer

Sponsors and support

Primary sponsor: MMC
Source(s) of monetary or material Support: Máxima MC

Intervention

Outcome measures

Primary outcome

Primary outcomes:
1. Feasibility of the multimodal prehabilitation program (without extending the time from MDT meeting to surgery beyond the DLCA-S norm of 3 weeks); defined as: ≥80% of participants completed a sufficient multimodal prehabilitation program (sufficient program defined as: ≥80% of goals reached).

2. The effect of the multimodal prehabilitation program on functional capacity, measured with the 6-minute walk test, steep ramp test and 1-repetition maximum at the end-of-program test moment (3-4 days before surgery), and during follow-up (6 weeks and 3 months after surgery) as compared to baseline and as compared to control subjects who did not participate in the multimodal prehabilitation program.

Secondary outcome

Secondary Objectives
To:
- Evaluate the complete program and per component, e.a. compliance and satisfaction;
- Determine cost effectiveness of the prehabilitation program;
- Determine the effectiveness of the program on nutritional and mental status, smoking cessation, patient optimization and reported Quality of Life (QoL) as compared to baseline and to the control group;
- Determine the effect on clinical outcome (mortality, length of stay, complication rate and re-admission rate) compared to control group and historical cohort as reported in DLCA-S 2018;
- Study the correlation between maximal oxygen uptake reported through the physical condition questionnaire and as determined with the steep ramp test and if applicable, cardiopulmonary exercise test.

Study description

Background summary

Rationale: Prehabilitation may improve functional capacity and nutritional status before surgery, resulting in enhanced recovery after surgery, reduced complication rates, improved quality of life and patient’s overall outcome. A prehabilitation program may consist of several interventions and should preferably be multimodal. Such a multimodal program was shown to be feasible, safe and able to improve functional capacity in patients with colorectal cancer. However, postponing surgery in order to undergo prehabilitation, cannot be recommended. Prehabilitation in patients with non-small cell lung cancer (NSCLC) undergoing anatomical lung resection has not been investigated before. These patient may benefit from multimodal prehabilitation, especially since the surgical resection affects a vital organ. In the Netherlands, the maximum waiting time between the multidisciplinary team (MDT) meeting and surgery is 3 weeks, according to the Dutch Lung Cancer Audit-Surgery (DLCA-S). Whether it is feasible to fit a prehabilitation program in this waiting time and whether it has effect on functional capacity is not yet known.

Objective: To determine whether the multimodal prehabilitation program (without extending the time from MDT meeting to operation beyond the DLCA-S norm of 3 weeks) for patients with NSCLC undergoing anatomical lung resection in MMC and ASz:
1. is feasible;
2. results in an increased functional capacity as measured with the 6-minute walk test, steep

ramp test and 1-repetition maximum at the end-of-program (approximately 3-4 days before surgery), and during follow-up (6 weeks and 3 months after surgery) as compared to baseline and as compared to control subjects who did not participate in the multimodal prehabilitation program.

Study design: Multicenter pilot study. A multimodal prehabilitation program starts the day after the MDT meeting (formal confirmation of eligibility for surgery) and ends at hospital admission for surgery. There are 4 test moments around the multimodal prehabilitation program: baseline (few days before start of program), end-of-program (3-4 days before surgery), 6 weeks after surgery and 3 months after surgery.

Study population: Patients with NSCLC ≥18 years of age, undergoing anatomical lung resection in MMC or ASz, with a straightforward preoperative work-up. N=10 patients per center will participate in the multimodal prehabilitation program. N=10 patients per center will be included in the control group, e.g. if they are not willing to participate in the program interventions. The control group takes part in the 4 test moments, but not in the program interventions.

Intervention:
Multimodal prehabilitation program, with a duration of approximately 3 weeks, consisting of:
1. Physical exercise
a) Endurance
b) Strength
2. Nutritional support
a) Optimization of nutritional status
b) Protein and vitamin supplementation
3. Mental support
a) Medical psychologist counselling
b) (Breath) relaxation exercises
4. Smoking cessation
5. Patient empowerment & education
6. Patient optimization (directed at affected organ system)
a) Inspiratory muscle training
b) Breathing and sputum clearance techniques

Primary outcomes:
1. Feasibility of the multimodal prehabilitation program (without extending the time from MDT meeting to surgery beyond the DLCA-S norm of 3 weeks); defined as: ≥80% of participants completed a sufficient multimodal prehabilitation program (sufficient program defined as: ≥80% of goals reached).
2. The effect of the multimodal prehabilitation program on functional capacity, measured with the 6-minute walk test, steep ramp test and 1-repetition maximum at the end-of-program test moment (3-4 days before surgery), and during follow-up (6 weeks and 3 months after surgery) as compared to baseline and as compared to control subjects who did not participate in the multimodal prehabilitation program.

Study objective

Prehabilitation may improve functional capacity and nutritional status before surgery, resulting in enhanced recovery after surgery, reduced complication rates, improved quality of life and patient's overall outcome. Patients with non-small cell lung cancer may especially benefit from prehabilitation since the surgical resection affects a vital organ.

Study design

There will be 4 test moments around the multimodal prehabilitation program:
- The first test moment is the baseline test moment, a few days before the start of the interventions of the multimodal prehabilitation program. The baseline test moment is needed to tailor the components of the multimodal prehabilitation program to the individual patient and to enable evaluation of the effect of the multimodal prehabilitation program on functional capacity.
- The second test moment is the end-of-program test moment, which takes place 3-4 days before surgery.
- The third and fourth test moments are follow-up test moments, at respectively 6 weeks and 3 months after surgery. 3 Months postoperatively will consist of questionnaires only.

Intervention

The multimodal prehabilitation program consists of 6 pillars:
1. Physical exercise
a. Endurance
b. Strength
2. Nutritional support
a. Optimization of nutritional status
b. Protein and vitamin supplementation
3. Mental support:
a. Medical psychologist counselling
b. (Breath) relaxation exercises
4. Smoking cessation
5. Patient empowerment & education
6. Patient optimization (directed at affected organ system)
a. Inspiratory muscle training
b. Breathing and sputum clearance techniques

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- ≥18 years of age
- NSCLC, pathologically confirmed or high suspicion of NSCLC, with an indication for anatomical lung resection
- Eligible for anatomical lung resection, that will be performed in MMC or ASz
- Straight forward preoperative work-up, with confirmation of eligibility for surgery by lung surgeon before the MDT meeting
- Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Inability to give written informed consent (illiteracy, language barrier, cognitive disabilities)
- Contra-indication for training (e.g. comorbid conditions, signs of undiagnosed cardiac disease, physical or psychological impairments)
- Renal insufficiency, defined as estimated Glomerular Filtration Rate (eGFR) <60 ml/min/1.73m2 (estimated using the Modification of Diet in Renal Disease (MDRD) formula in the MMC and estimated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula in the ASz)
- Participation in MEDIAST trial (NTR6528; NL60692.015.17)
- In case of patients in ASz: referral by pulmonologist from Beatrix hospital, Gorinchem (the Netherlands) for surgery in ASz

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

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Ethics review

Positive opinion

Date:	10-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48205
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8080
CCMO	NL70578.015.19
OMON	NL-OMON48205

Study results

Summary results

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