

Multimodal prehabilitation in NSCLC patients undergoing surgery

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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...

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

Samenvatting

ID

NL-OMON21254

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

Non-small cell lung cancer

Ondersteuning

Primaire sponsor: MMC

Overige ondersteuning: Máxima MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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: $\geq 80\%$ of participants completed a sufficient multimodal prehabilitation program (sufficient program defined as: $\geq 80\%$ 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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: $\geq 80\%$ of participants completed a sufficient multimodal prehabilitation program (sufficient program defined as: $\geq 80\%$ 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blinding: Open / niet geblindeerd
Controle: Actieve controle groep

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 06-01-2020
Aantal proefpersonen: 40
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

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Ethische beoordeling

Positief advies
Datum: 10-10-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48205
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8080

Register

CCMO

OMON

ID

NL70578.015.19

NL-OMON48205

Resultaten

Samenvatting resultaten

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