Multicenter pilot study to determine the feasibility of a multimodal prehabilitation program in patients with non-small cell lung cancer undergoing anatomical lung resection

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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....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48205

Source
ToetsingOnline

Brief title
Multimodal prehabilitation in NSCLC patients undergoing surgery

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, Non-small cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: De ziekenhuizen zorgen elk voor eigen financiering binnen het ziekenhuisbudget. De kosten worden opgevangen in de begroting van de betreffende afdelingen. Er is toestemming verleend door de betrokken managers. De eiwitsupplementen worden verschaft door Friesland Campina (zoals bij PREHAB trial NL58281.015.16)

Intervention

Keyword: Anatomical lung resection, Feasibility, Multimodal prehabilitation, Non-small cell lung cancer

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 at the end-of-program test moment (3-4a few days before surgery), and

during follow-up (6 weeks and 3 months after surgery) as compared to baseline

and the control group.

1. Feasibility:

The multimodal prehabilitation program is considered feasible if at least 80%

of participants (n=8 out of 10 in both centers) underwent at least a sufficient

program. A sufficient program is defined as a program in which at least 80% of

the goals is reached, as presented in Table 3 in the study protocol. The

maximum number of appointments that is offered might differ per patient, e.g. if surgery is planned earlier than 3 weeks after the MDT meeting. In that case, feasibility for that patient will be calculated as *80% of the total number per component for that individual patient.

For physical exercise, nutritional support and patient optimization the baseline test moment is mandatory to enter the multimodal prehabilitation program, because these interventions are tailored for the individual patient based on the baseline test moment (SRT, 1RM, BIA and MIP). Therefore, the baseline test moment is incorporated in the definition of feasibility.

Feasibility per patient who participated in the multimodal prehabilitation group, will be determined after all data on compliance have been collected (number of attended supervised training sessions recorded, copy of patient's handbook (number of LIT and nutritional supplementation intake rec-orded) and accelerometer read-out (LIT)), i.e. during hospital admission for surgery. Feasibility of the multimodal prehabilitation program will be evaluated per center and for the entire study group of patients participating in the multimodal prehabilitation program after the last patient has completed the program (at time of surgery). Obviously, feasibility will not be determined in the control group.

2. Functional capacity:

Improvement of functional capacity after participating in the multimodal

prehabilitation program will be measured at the end-of-program test moment (3-4 days before surgery) and during follow-up at 6 weeks and 3 months after surgery and will be compared to the baseline test moment and to the control group, using the following tests: (explained in detail in 8.3.2)

i. Steep ramp test (SRT)

ii. 6 Minute walk test (6MWT)

iii. One repetition maximum (1-RM)

Secondary outcome

- 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) in comparison with 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

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.

Study 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 (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.

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

Study burden and risks

Due to careful patient selection, application of exclusion criteria and the fact that patients are deemed eligible for surgery after determining operability as part of the preoperative work-up, potential risks of the study are diminished. Anticipated risks are muscle/tendon injury from exercises, transient tiredness and some minor discomforts related to nutritional supplementation.
The maximum burden of the multimodal prehabilitation program is in case of a complete program: 4 hospital visits for test moments, 7 hospital visits for supervised training sessions, questionnaires at 4 test moments, 12 homebased training days, 20 days of nutritional supplementation. For the control group the burden will be: 4 hospital visits for test moments (including physical examination and undergoing the study tests) and questionnaires at 4 test moments.
Hospital visits for the study will be combined with hospital visits for clinical purposes.
The anticipated benefit from the study in the group participating in the multimodal prehabilitation program is an improved functional capacity and nutritional status, and empowerment in the disease process, which in turn will improve clinical outcome and quality of life.
For patients in the control group the anticipated benefit is insight in their functional capacity, which might stimulate to exercise on an independent basis.
This study can only be done in patients with NSCLC undergoing anatomical resection, because a prehabilitation program has not been investigated in this population, which is distinctly different than e.g. patients with colorectal cancer. Determining feasibility in this patient group is important since a shorter waiting time until surgery is employed in this patient group than in patients with colorectal cancer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- *18 years of age
- NSCLC, pathologically confirmed or high clinical suspicion
- 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 multidisciplinary team meeting
- Written informed consent

Exclusion criteria

- 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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21254
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70578.015.19
OMON	NL-OMON21254