THE MUSCLE POWER STUDY - surgery related muscle loss and muscle strength after complex abdominal surgery for pseudomyxoma peritonei, pancreatic, liver and colorectal cancer

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46139

Source
ToetsingOnline

Brief title
THE MUSCLE POWER STUDY

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign
- Gastrointestinal therapeutic procedures

Synonym
Surgical Related Muscle Loss (SRML)

Health condition

chirurgisch gerelateerd spierverlies

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Major abdominal surgery, Quality of life, Surgery related muscle loss, Ultrasound

Outcome measures

Primary outcome

Our main objective is to measure the amount of clinically relevant SRML

(defined as *5% muscle loss within one week measured by the CSA of the

different muscles) in cancer patients after major abdominal surgery for

pseudomyxoma peritonei, pancreatic, liver and colorectal cancer by using

bedside ultrasound and squeeze and force measurements of arms and legs.

Secondary outcome

For the different secondary endpoints the included group of patients will be

divided in two subgroups:

* Clinically relevant SRML (*5% muscle loss within seven days) and

* Clinically not relevant SRML (< 5% muscle loss within seven days)

Our secondary objectives will be the difference - within our two subgroups -

between :

1. Mean SRML per day (during hospital stay);

2. Mean loss of muscle strength per day (during hospital stay);

3. SRML patterns over 10 days;

4. Identifying whether the following points are risk factors for clinically

relevant SRML;

a. Age * 65 years

b. Sarcopenia measured preoperatively by CT scan (exact definition and

measurement method described in chapter 9.3.5.3)

c. Diabetes preoperatively

d. Major postoperative complications (Clavien-Dindo * III)

e. Insufficient physical activity: <150 minutes moderate or vigorous intensity

physical activity during the first seven days after surgery

f. Insufficient protein intake: intake of protein less than 1.5 gram per

kilogram per day during two or more days within the first week after surgery

5. Correlation of urinary creatinine excretion rate (CER);

6. Unplanned readmissions to the hospital within 30 days after discharge;

7. The influence on quality of life and fatigue after three and six months

Study description

Background summary

Acute muscle loss in critically ill patients is associated with significant morbidity and mortality and predictive of long-term functional disability. Up to now, only three studies examined acute Surgery Related Muscle Loss (SRML) in surgical cancer patients. At least one out of three cancer patients will have *10% muscle loss within one week after major abdominal surgery. There is no global consensus about which amount of muscle loss is clinically relevant (e.g. harmful for the patient). Definitions in scientific publications vary from *2.7 to *10% loss of muscle mass within one week after surgery. SRML seems to be associated with several short-term postoperative outcomes and negatively affects Quality of Life (QoL) and fatigue postoperatively. At this moment only

two risk factors for SRML have been identified (age *65 years and diabetes preoperatively).

Study objective

The aim of this study is to investigate the amount of clinically relevant SRML (defined in this study as *5% muscle loss within one week measured by the cross sectional area (CSA) of the different muscles) in patients after major abdominal surgery for pseudomyxoma peritonei, pancreatic, liver and colorectal cancer by using bedside ultrasound and squeeze and force measurements of arms and legs. At the same time, possible risk factors for clinically relevant SRML will be analyzed and correlated to the effect of clinically relevant SRML on fatigue and QoL after three and six months.

Study design

We will conduct an observational cohort study in the UMCG including the surgical oncology and hepatic pancreatic biliary surgery departments. The study will run from December 2018 until December 2020 and 180 patients will be included. After informed consent is given, the patient will be included into the study. One day before surgery the patient will undergo a series of tests consisting of: two quality of life questionnaires (The World Health Organization Quality of Life (WHOQOL-Bref) and RAND 36-item Health Survey (RAND-36)) and a fatigue questionnaire (Multidimensional Fatigue Inventory, MFI-20), squeeze and force measurements of arms and legs to determine muscle strength, 24-hour urine collection to determine the urinary creatinine excretion rate and ultrasound measurements of four muscles (m. biceps brachii, m. rectus abdominis, m. rectus femoris and m. vastus intermedius) to estimate baseline muscle mass by measuring the CSA. The ultrasound and squeeze and force measurements will be repeated on the 3th, 7th and 10th day after surgery and on the day of discharge. During hospital stay physical activity of each patient will be monitored by using an activity tracker attached to the ankle of the patient. Also protein intake during hospital stay will be monitored every day by a dietician. Three and six months after hospital discharge, the patient will be seen in the outpatient clinic to repeat the quality of life and fatigue questionnaires. Basic patient, operation and postoperative characteristics will be collected from digital patient records.

Six possible risk factors for clinically relevant SRML were previously identified by literature or expert opinion, consisting of: sarcopenia preoperatively, diabetes preoperatively, age *65 years, major postoperative complications (Clavien-Dindo * III), insufficient physical activity and insufficient protein intake. Three possible risk factors (age, diabetes preoperatively, and major postoperative complications) will be collected from digital patient records. The presence of sarcopenia preoperatively will be measured on preoperative workup CT scans by a musculoskeletal radiologist

according to the latest guidelines. Physical activity during hospital stay will be monitored by an activity tracker. Insufficient physical activity is defined according to the Dutch movement guideline for the health council: less than 150 minutes of moderate/vigorous intensity physical activity (<2020 counts/min) per seven days. Protein intake per day is calculated by a dietician. According to the European Society for Clinical Nutrition and Metabolism guidelines surgical patients need 1.5 gram/kilogram protein per day after major surgery. Insufficient protein intake is defined as an intake less than 1.5 gram/kilogram/day during two or more days within the first week after surgery. Each of these six possible risk factors will be registered dichotomously (yes/no). Association between the presence of a possible risk factor the occurrence of clinically relevant SRML will be investigated.

Study burden and risks

Since the measurements consist of a combination of standard measuring methods that do not carry risks with them, it is extremely unlikely that adverse events will occur during the study period. The burden for patients consists of seven different measuring points, including one preoperatively, four during hospital stay after surgery, and two in the outpatient clinical three and six months after surgery. All visits are standard care in the Netherlands so patients have no additional scheduled visits. QoL (WHOQOL-Bref and RAND-36) and fatigue (MFI-20) questionnaires will be assessed at baseline, and three and six months after surgery. The expected burden is 60 minutes per time point. No new investigational treatment with possible risks is being used.

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

* Female or male aged at least 18 years;
* The patient must speak the Dutch language;
* The patient understands the purpose of the study and has given written informed consent to participate in the study;
* Diagnosed or the suspicion of a liver tumour (primary cancer or colorectal liver metastases), pancreatic malignancy, bile duct malignancy, colon tumour, rectum tumour, or pseudomyxoma peritonei;
* Scheduled for open major abdominal surgery consisting of the following surgical procedures:
o Cytoreductive surgery combined with hyperthermic intraperitoneal intraoperative chemotherapy) (CRS with HIPEC)
o (Sub)total pelvic exenteration
o Pylorus preserving pancreaticoduodenectomy (PPPD)
o Whipple procedure (classic pancreaticoduodenectomy)
o Subtotal pancreatectomy
o Total pancreatectomy
o Major liver resection, defined as *3 liver segments
* The patient will be operated at the UMCG;
* Presence of a preoperative CT-scan of the abdomen.

Exclusion criteria

* Scheduled for laparoscopic surgery;
* Minor liver resections, defined as <3 liver segments;

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	07-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL65843.042.18