Cancer rehabilitation for Hepato-Pancreato-Biliary cancer patients undergoing surgical treatment

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON46733

Source
ToetsingOnline

Brief title
CREST study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Miscellaneous and site unspecified neoplasms benign

Synonym
frailty, increased vulnerability towards stressors

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: frailty, hepatobiliary cancer, rehabilitation

Outcome measures

Primary outcome

General fatigue, assessed with the Multidimensional Fatigue Inventory (MFI).

Secondary outcome

Secondary outcomes are quality of life, cardiopulmonary fitness, skeletal

muscle mass and strength, frailty, anxiety, depression, performance status, and

body weight. Furthermore, overall survival will be assessed.

Study description

Background summary

In gastrointestinal cancer patients, overall almost 30% of patients experience severe fatigue while in HPB cancer the vast majority suffers from fatigue. Generally, even after successful cancer treatment, 19 to 38% of disease-free cancer survivors remain fatigue, which underlines its persistent character. The cancer itself, as well as the sequelae after surgical interventions or chemotherapy may lead to physical and psychosocial impairment in cancer patients. As patients experience increased fear and a lower exercise tolerance due to persistent fatigue they are at great risk of spiralling down a vicious circle which progressively enhances these symptoms and further impairs their quality of life and self-management capacity. In patients who have been treated for cancer, psychotherapy and physical exercise are shown to reduce fatigue complaints.

Study objective

Since multiple dimensions (physical, emotional and cognitive) seem to be involved in the pathophysiology of fatigue, multidimensional approach to alleviate will probably have a synergistic effect. Previous studies supporting this assumption included general cancer populations or breast and colon cancer patients, who are known for their relatively good prognosis and post-treatment functional outcome.
The purpose of our study is to investigate whether a postoperative

rehabilitation program (solution focused psycho- and physical exercise therapy) improves fatigue (primary outcome) and quality of life, muscle mass, and physical fitness (secondary outcomes) in cancer patients operated for HPB malignancies, known to have a more dismal prognosis.

Study design

In this multicentre randomized controlled trial, patients will randomly be assigned to the treatment (rehabilitation program) or control (usual care) group in the four participating centres. After hospital discharge, the treatment group will undergo a supervised, tailored exercise program aimed at both cardiorespiratory fitness (aerobic training) and muscle strength (resistance training) twice a week during twelve weeks. Furthermore, one hour solution focused therapy is offered every other week. The primary outcome will be fatigue, assessed using the Multidimensional Fatigue Inventory assessed 6 and 12 months after surgery. Secondary outcomes are quality of life, cardiopulmonary fitness, skeletal muscle mass and strength, frailty, anxiety, depression, and body weight, assessed preoperatively, at the start and end of the rehabilitation program and six and twelve months after surgery. Validated tests are used to assess these parameters. Furthermore, an effect of the intervention on overall survival will be investigated.

Intervention

rehabilitation program consisting of physical exercise therapy, psychotherapy and dietary consultation.

Study burden and risks

risk associated with participation:
- potential increase in fatigue.

Furthermore participation will imply:
- that the patient will spend extra time
- that the patient has to fill in potentially confronting questionaires
- that the patient will have to adhere to the instructions and additional meetings

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

* Undergoing curative intent surgery for HPB malignancies. Liver surgery will be defined as major if a left or right (extended) hemihepatectomy or if 3 or more segments are resected and minor if less than 3 segments are resected.
* Clinically suspect or histologically confirmed liver, bile duct, pancreatic carcinoma or invasive IPMN;
* Life expectancy of at least six (6) months;
* Resection performed
* Fatigue score * 4 on a numeric rating scale (NRS) with scores of 0 to 10
* Able to read and understand the Dutch language;
* Written informed consent.

Exclusion criteria

- Bone metastases or other high risk of fracture;
- Not able to perform basic activities of daily living (ECOG *3);
- Decompensated heart disease, uncontrolled hypertension (systolic blood pressure > 200 mmHg or diastolic blood pressure > 110 mmHg), heart failure (NYHA Class II or greater) or chronic obstructive pulmonary disease causing fatigue;

- Living in nursing homes;
- Cognitive impairment;
- BMI <15 kg2/m2, >5% weight loss per month or other health problems that would not allow physical exercise training;
- Anxiety or depression requiring psychiatric consultation;
- Cancer treatment in the previous 3 years (except basal skin cancer);
- Participation in other studies containing elements of physical exercise or psychological therapy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2018
Enrollment:	154
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL64296.078.17