Cancer Rehabilitation in hepato-pancreato-biliary cancer patients undergoing Surgical Treatment.

No registrations found.

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

Summary

ID

NL-OMON21906

Source
Nationaal Trial Register

Brief title
CREST

Health condition

hepato-pancreato-biliary cancer, HPB, fatigue, quality of life, muscle mass, rehabilitation.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Zon Mw

Intervention

Outcome measures

Primary outcome

MFI-20 General Fatigue at 12 months after surgery

Secondary outcome

MFI-20, Quality of life, Frailty, Anxiety and Depression, physical status, activity level, survival, cost-utility

Study description

Background summary

Rationale: 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.

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 multi centre 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 MFI-General Fatigue, at 12 months after surgery. Secondary outcomes are
quality of life, cardiopulmonary fitness, skeletal muscle mass and strength, distribution and intensity of
physical activity, MFI-Physical Fatigue, MFI-Mental Fatigue, MFI-reduced activity and motivation, frailty,
anxiety, depression, and body weight, and risk of malnutrition 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.

Study population: Adult HPB cancer patients undergoing surgical cancer resection in Erasmus MC
(Rotterdam), AMC (Amsterdam), LUMC (Leiden), and UMCG (Groningen) will be included in this study.
Intervention : rehabilitation program consisting of physical exercise therapy, psychotherapy and dietary
consultation.

Main study parameters/endpoints: General fatigue at 12 months after surgery, assessed with the
Multidimensional Fatigue Inventory (MFI).

Study objective

Post-operative rehabilitation consisting of physiotherapy and solution focused therapy will reduce fatigue, improve quality of life and inrease muscle mass in surgically treated HPB patients.

Study design

2, 8, 16 weeks after discharge and 6, 12 months after surgery

Intervention

Physical therapy: Every week 2x 2hr for 12 weeks,

At home Solution Focused Therapy: Every other week 1x 1hr for 12 weeks.

Diatary support: if at risk for malnutrition

Contacts

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Eligibility criteria

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 or pancreatic carcinoma;

• Life expectancy of at least six (6) months;

• 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

• Treatment with adjuvant chemo(radiation)therapy

• Bone metastases or other high risk of fractures;

• 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 5 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)
Control:	Active

Recruitment

NL
Recruitment status: Other

Start date (anticipated):	01-04-2018
Enrollment:	154
Type:	Unknown

Ethics review

Positive opinion Date:	28-03-2018
Application type:	First submission

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
NTR-new	NL6941
NTR-old	NTR7137
Other	844001 319 projectnummer ZonMw : MEC-2018-008 METC ErasmusMC /

Study results