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

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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.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21906

Bron
NTR

Verkorte titel
CREST

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Zon Mw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

MFI-20 General Fatigue at 12 months after surgery

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-04-2018
Aantal proefpersonen:	154
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	28-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6941
NTR-old	NTR7137
Ander register	844001 319 projectnummer ZonMw : MEC-2018-008 METC ErasmusMC /

Resultaten