Predictive factors for sarcopenia and malabsorption in high risk surgical oncological patients after cytoreductive surgery and HIPEC procedure

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To investigate the predictive factors for sarcopenia in high risk surgical oncological patients undergoing a CRS + HIPEC procedure. The secondary goal is to investigate the predictive factors for malabsorption and the incidence of anastomic leakage...

Ethical review	Approved WMO
Status	Completed
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON42927

Source
ToetsingOnline

Brief title
Sarcopenia and Malabsorption in HIPEC patients (SMAL-HIPEC)

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Electrolyte and fluid balance conditions

Synonym
muscle loss and HIPEC procedure

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: Cancer, HIPEC, Malabsortpion, Sarcopenia

Outcome measures

Primary outcome

Sarcopenia (Muscle loss), measured by the psoas muscle density is the primary outcome

Secondary outcome

Malabsorption, measured by the fecal energy by bomb calorimetry [kcal/d] is the secondary outcome.

Other endpoints are anastomic leakage, pneumonia, infection, length of hospital stay, readmission rate, and one-year survival.

Study description

Background summary

Cytoreductive surgery (CRS) in combination with hyperthermic intraperitoneal chemotherapy (HIPEC) provides a promising therapeutic strategy for patients with gastrointestinal cancer. Sarcopenia and malabsorption are common in patients after CRS + HIPEC surgery and are associated with an increase on postoperative complications. therefore, this study aims to investigate the predictive factors for sarcopenia and malabsorption in high risk surgical oncological patients undergoing a CRS + HIPEC procedure

Study objective

To investigate the predictive factors for sarcopenia in high risk surgical oncological patients undergoing a CRS + HIPEC procedure. The secondary goal is to investigate the predictive factors for malabsorption and the incidence of

anastomic leakage, pneumonia, infection and length of hospital stay, readmission rate and survival in these patients, one year after surgery.

Study design

A one-year observational study

Study burden and risks

5x measuring upper arm and handgrip strength
5x physical examination and questions about nutrition (PG_SGA) (5 minutes)
3 x questionnaire quality of life (5 minutes)
3x collection 24-hour urine
2x keep their dieet steady and notate their food intake during 4 consecutive days and collection of feces on 2nd, 3rd and 4th day (bomb calorimetry)
2x analysis of oxygen and cardioxide while lying on a bed (15 minutes) (indirect calorimetry)
3x 2 extra tubes of blood
Wear a pedometer for 2 days prior to visiting the surgeon

All these test together will take about 3 hours to complete. The blood donation can cause pain and bruising. Their is no extra punction needed for this donation. Keeping the diet steady for 4 consecutive days and collect the stool can be burdensome for the patient.

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

Patients > 18 years that undergo CRS and HIPEC procedure at the University Medical Center Groningen (UMCG)

Exclusion criteria

All patients not eligible for CRS and HIPEC procedure
not fit for surgery or
unable to provide written consent or inability to fill out questionnaires

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-10-2017
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2016
Application type:	First submission
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

ID: 28190
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57812.042.16
OMON	NL-OMON28190