Hoe is de opname van voeding bij mensen die een HIPEC ondergaan?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28190

Source
Nationaal Trial Register

Brief title
SMal-HIPEC

Health condition

Patients diagnosed with abdominal cancer and treated with cytoreductive surgery (CRS) and a hyperthermic intraperitoneal chemotherapy (HIPEC) procedure

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: still pending: UMCG

Intervention

Outcome measures

Primary outcome

Sarcopenia defined as the degenerative loss of skeletal muscle mass that can be quantified by the CT measurement of the psoas muscle surface, normalized for patient height [cm2 m−2].

Secondary outcome

• Malabsorption

• Loss of muscle mass, measured by handgrip strength; arm circumference & triceps skinfold thickness; creatinin & urea in 24-hour urine.

• Incidence of Clavien Dindo complications

• Length of hospital stay and re-admittance rate

• Survival

• Quality of Life

Study description

Background summary

In this explorative observational study we will study the predictive factors for sarcopenia and malabsorption in patients with abdominal cancer undergoing cytoreductive surgery (CRS) combined with hyperthermal intraperitoneal chemotherapy

Study objective

Possible predictive factors for sarcopenia (primary outcome) could be: 1. The length and part of the resected small intestine, 2. Adjuvant (and type of) chemotherapy postoperatively, 3. Complications (like sepsis), 4. Nutritional intake (Energy and protein), 5. Preoperative muscle loss (sarcopenia), 6. Movement.

Possible predictive factors for malabsorption (secondary outcome) could be 1. The length and part of the resected small intestine 2. Adjuvant (and type of) chemotherapy postoperatively 3. Small intestinal bacterial overgrowth, especially when the ileocecal valve dysfunctions

Study design

Sarcopenia will be measured before surgery and 12 months after surgery.

The other endpoints will be registered at 3 and 6 months after surgery as well

Intervention

None, this is an explorative observational trial

Contacts

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Eligibility criteria

Inclusion criteria

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

• Written informed consent

• Age > 18 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Not fit for surgery

• Inability to provide written consent or inability to fill out questionnaires

• Karnofsky Performance Status < 80

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42927
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5961
NTR-old	NTR6327
CCMO	NL57812.042.16
OMON	NL-OMON42927

Study results