Peri-operative Energy and Protein BALANCE in colorectal cancer patients undergoing a liver resection

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44421

Source
ToetsingOnline

Brief title
PEP Balance

Condition

- Other condition

Synonym
peri-operative energy balance

Health condition

peri-operational energy balance + cancer cachexia

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,under consideration of Nutricia Research Foundation

Intervention

Keyword: energy balance, nutrition, peri-operative, protein balance

Outcome measures

Primary outcome

Main study parameters are energy balance (calculated as difference between food intake and energy expenditure and from changes in body composition), body composition (measured using DEXA, CT and BIA), metabolic markers (measured in fat and muscle biopsies), biochemical markers (measured in blood/serum), muscle function parameters (grip strength and measured in a biopsy) and gene expression (transcriptomic and PCR analyses of fat and muscle biopsies).

Secondary outcome

Not applicable

Study description

Background summary

Undernutrition in hospitalized patients defined as low BMI (BMI < 18.5) or unintended weight loss, poses a risk for increased morbidity and mortality. The prevalence of undernutrition in surgical patients is estimated to be 25%-40%. To reduce undernutrition, optimal perioperative nutritional support in hospitalized patients is needed. Therefore, an accurate estimate of energy expenditure during different stages in the peri-operative process is relevant. In cancer patients, cachexia plays an additional role in the maintenance of energy balance and protein balance. Cachexia is a complex metabolic syndrome characterized by clinically relevant loss of muscle mass with or without loss of fat mass. In cachexia, restoring the balance between

energy intake and energy consumption is key to a proper treatment program1. Currently, not much is known on the additional negative effects of a surgical procedure on energy metabolism in patients with a tumor that can induce cachexia.

Study objective

The first aim of this study is to investigate and validate energy expenditure using DLW in colorectal cancer patients before and after a liver resection and to estimate energy balance from the change in body composition.
The second main aim of the study is to investigate the relation between energy metabolism, changes in body composition as measured by repeated CT-scans and the functional and metabolic parameters influencing cachexia.

Study design

Observational study

Study burden and risks

The condition of the patients and the planned operation can cause adverse effects. However, we expect no additional risk for the subjects due to the proposed measurements. For the sampling of blood, there is a small risk of bruising. Harvest of biopsies occurs during the planned operation and is not expected to cause a significant increase in burden for the patient. All other measurements are non-invasive, observational measurements with no risk of any harmful side effects.

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

• Colon cancer with liver metastases.
• Eligible for a liver resection procedure.

Exclusion criteria

• Being abroad for more than one week during the month preceding the surgery
• Suffering from malabsorption
• Having an artificial cardiac pacemaker
• Laparoscopic surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	30-12-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	08-06-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL50557.081.14