Pre- and postoperative energy expenditure in major liver resection: what do we ask from a patient?

Published: 22-07-2022 Last updated: 02-12-2024

The aim of the study is to gain more insights into the metabolic demand and possible changes thereof pre- and postoperatively. Additionally, data on aerobic fitness and activity levels will be gathered.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56217

Source ToetsingOnline

Brief title PRO-NRG

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym

liver malignancy, liver metastases

Research involving Human

Sponsors and support

Primary sponsor: Universiteit Maastricht Source(s) of monetary or material Support: Ministerie van OC&W

1 - Pre- and postoperative energy expenditure in major liver resection: what do we a ... 3-05-2025

Intervention

Keyword: energy expenditure, liver resection

Outcome measures

Primary outcome

The main study parameter is the difference of energy expenditure pre- and

postoperatively, as measured with doubly labelled water and indirect

calorimetry.

Secondary outcome

Additionally, aerobic fitness, physical activity level, metabolic factors in

blood, and postoperative complications will be assessed.

Study description

Background summary

Complication rates after major liver resections remain as high as 43%. Many initiatives have been taken to reduce postoperative morbidity. As such, prehabilitation programmes are increasingly used for patients undergoing major abdominal surgery. Improvement of aerobic fitness has been proven to reduce complication rates, especially in high-risk patients (those with a low preoperative aerobic capacity). Different conceptual hypotheses exist of the underlying mechanism of variability in postoperative complications and prehabilitation response. One of the complementary rationales focusses on homeostasis-allostasis before and after surgery, more specifically on the preoperative aerobic capacity to meet postoperative metabolic demands. However, more insight in postoperative metabolic demands (energy expenditure) during in-hospital recovery from major abdominal surgery in relation to preoperative resting metabolic demands and maximal aerobic capacity is essential to understand the increase in metabolic demands coinciding with major surgery in relation to the body*s reserve capacity. This information can be used to better understand the rationale behind exercise prehabilitation, as well as to optimize the content of preoperative treatment for unfit patients, for instance by means of personalized prehabilitation programmes that might improve postoperative outcomes.

Study objective

The aim of the study is to gain more insights into the metabolic demand and possible changes thereof pre- and postoperatively. Additionally, data on aerobic fitness and activity levels will be gathered.

Study design

The study will be a prospective observational study with thorough pre- and postoperative measurements of energy expenditure. Energy expenditure will be measured using the doubly labelled water method, as well as by indirect calorimetry. To assess aerobic capacity, cardiopulmonary exercise testing will be performed pre- and postoperatively. Additionally, accelerometers will be used to evaluate pre- and postoperative physical activity levels . Blood samples will be collected to analyze metabolic factors in the blood.

Study burden and risks

The study poses a low risk on the patients. Doubly labelled water has a low burden (intake of doubly labelled water and collecting urine samples) and has been proven safe for use in humans in many clinical studies. Therefore, the risks associated with this measurement is very low. Indirect calorimetry to determine pre- and postoperative resting energy expenditure is safe and has a low participant burden (30 min of resting measurements in supine position at 5 different time points). Cardiopulmonary exercise testing will be performed 7 days before surgery and at hospital discharge under supervision of trained professionals in safe circumstances. The risk for patients is considered to be low. To monitor physical activity levels pre- and postoperatively during the observational period (7 days preoperatively and 7 days postoperatively), wearable sensors (accelerometers) will be used. The burden for patients is minimal. Preoperatively there is one extra visit to the clinic. Overall, the planned measurements will not pose low risk to patients. However, given the intensity of assessments there might be a considerable burden for patients.

Contacts

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3 - Pre- and postoperative energy expenditure in major liver resection: what do we a ... 3-05-2025

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

o Age >=18 years
o Scheduled for liver resection (>=3 segments) at the MUMC+
o Able to understand the Dutch language sufficiently to give consent and follow orders during study assessments

Exclusion criteria

o Cirrhotic liver, Child Pugh B-C

o Unable or unwilling to perform CPET or indirect calorimetry

o Liver ablation as the primary treatment

o Termination of surgery due to too extensive oncological disease (open-close surgery)

Study design

Design

Study type:Observational invasiveMasking:Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	07-05-2024
Enrollment:	20
Туре:	Actual

Medical products/devices used

Registration:	No
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Ethics review

Approved WMO	
Date:	22-07-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	17-06-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO **ID** NL78760.068.21