Predictors for operation tolerance in elderly patients with coloncancer

Published: 01-02-2013
Last updated: 24-04-2024

To identify relevant geriatric assesment tests to develop a clinical instrument for predicting tolerance defined as the change of developing a complication in elderly patients (>=70 years) with a coloncarcinoma that recieve surgical treatment for...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37086

Source
ToetsingOnline

Brief title
P-TOP2

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colon cancer, colon carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: coloncarcinoma, elderly, frailty, Predicting

Outcome measures

Primary outcome

Primary outcome of the study is morbidity, defined as complication rate.

Complications will be registered according to the Dutch Surgical Colorectal

Audit (DSCA), following the LHCR grading system. Both general as surgical

complications are included.

Secondary outcome

Secundary outcomes are: 30 day mortality, only surgical complications, only

general complications, complications requiring re-intervention, quality of life

3 months after surgery, in-hospital stay, stoma, discharge to the patients own

house or institution, and ADL dependency.

Study description

Background summary

In western countries (like the Netherlands) the number of people of advanced age is rapidly increasing . Advanced age is associated with developing cancer. In a relatively high percentage the malignancy is situated in the colon. Elderly represent a very heterogeneous group. With increasing age, physiological reserves decrease and people become more vulnerable to disease and stress. However the pace of this declining process varies significantly between individuals, therefore high age is an exclusion criterion for many clinical trials. Little research is done in elderly cancer patients and little is known about this growing patient group. In this modern age of targeted therapy and individualized cancer care oncologists need objective and validated clinical tools which can accurately discriminate between fit and frail elderly patients to determine which patients will tolerate surgical treatment.

Study objective

To identify relevant geriatric assesment tests to develop a clinical instrument for predicting tolerance defined as the change of developing a complication in elderly patients (>=70 years) with a coloncarcinoma that recieve surgical treatment for their illness.

Study design

We will perform a multicentre (St. Antonius Hospital, Nieuwegein,and Tergooi Hospital Blaricum) prospective cohort study. To develop the predicting model, validated geriatric questionares (for health and functioning) and short mobility test (timed up and go test) derived from geriatric medicine will be used. Patients will be asked to complete these test before surgery. Furthermore 3 months after surgery the quality of life questionnaires will be repeated. Additional informtion will be derived from the patients charts. No additional bloodsamples or other interventions will not take place.

Study burden and risks

it is expected that participation in this study will have no advantages or disadventages for the patients. For completing the questionares two times a time investment of 30 to 60 minutes will be necessary. The study will not interfere with the treatment of any patient. There will be no interventions in this study.

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 with a coloncarcinoma that are eligble for surgery based on their illness.
-Patients aged 70 years or older at the date of surgery
-Operations that have the purpose to establisch a primary anastomosis or a (temporary) stoma.
-Laparoscopic and open surgeries
-informed consent.

Exclusion criteria

-Patients that are not capable to participate in the study because of poor understanding and speaking of the Dutch language
-Patients that are not capable to participate in the study because of cognitive impairment.
-Non elective surgery (meaning emergency surgery)
-If the predetermined purpose of the surgery is debulking and not resection.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	184
Type:	Anticipated

Ethics review

Approved WMO Date:	01-02-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL42269.100.12