Preoperative risk estimation for onco-geriatric patients
a clinical trial for the comparison of different preoperative assessment tools in the elderly surgical patient

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This study will be performed to test the predictive value of the GFI, the VES-13 and the timed *up and go* test compared to components of PACE in elderly patients of the age of 70 years and above undergoing surgery for a solid tumour.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON32521

Source
ToetsingOnline

Brief title
Preoperative risk estimation for onco-geriatric patients

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym
cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: het onderzoek wordt niet gefinancieerd: zie bij opmerkingen

Intervention

Keyword: onco-geriatric patient, preoperative assessment

Outcome measures

Primary outcome

Primary endpoint will be 30 day morbidity and mortality.

Secondary outcome

Secondary endpoints will be length of hospital stay and the number of

additional specialists involved in patient care in the 30 days after surgery.

Study description

Background summary

The majority of patients undergoing surgery for a solid tumour are over the age of 701. About 30% of these patients can be considered frail. They have comorbidities and are at a higher risk of developing postoperative complications and experience functional loss. So far there is no simple screening tool that allows the treating physician to identify those patients most at risk of developing postoperative problems. Identifying those at risk is a first step in the process towards preventing unnecessary postoperative complications such as delirium, cardiovascular complications and overall functional loss leading to loss of independency.
Several tools have been shown to be promising in this respect. The Preoperative Assessment of Cancer in the Elderly (PACE) has been shown to be predictive of 30 day morbidity2. Poor health in relation to disability assessed using the Instrumental Activities of Daily Living (IADL), fatigue and performance status (PS) were associated with a 50% increase in the relative risk of postoperative complications. Multivariate analysis identified moderate/severe fatigue, a dependent IADL and an abnormal PS as the most important independent predictors of post-surgical complications. Disability assessed by Activities of Daily

Living (ADL), IADL and PS were associated with an extended hospital stay

Study objective

This study will be performed to test the predictive value of the GFI, the VES-13 and the timed *up and go* test compared to components of PACE in elderly patients of the age of 70 years and above undergoing surgery for a solid tumour.

Study design

This is a multi-centre prospective cohort study collecting descriptive data across international centres for patients aged >70 years who are candidate to undergo elective cancer surgery.Patients will be stratified according to tumour localisation: intra cavity (e.g. colorectal, gynaecological) vs superficial (e.g. breast, head & neck, melanoma).
The combination of components of PACE, the timed *up and go* test, the VES-13 and the GFI will be administered to every patient within two weeks prior to the surgical procedure

Study burden and risks

There are no known risks or benefits associated with participation. The patient will be required to answer some questions and walk a few meters which will take a total of approximately 30 minutes.

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

aged > 70 years, elective surgical cancer treatment, under general anesthesia, give written inforemd consent

Exclusion criteria

patients requiring emergency surgical management within 24 hours
unable to give written informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2009

Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	11-05-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	4635
CCMO	NL25936.058.08