A randomized controlled trial of geriatric liaison intervention in frail surgical oncology patients

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Objective: The primary objective of this study is to show that early detection of geriatric patients at risk of preventable functional decline following a surgical procedure under general anesthesia for a solid tumor, combined with a geriatric...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30407

Source
ToetsingOnline

Brief title
geriatric intervention

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym
cancer in the elderly

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cancer, frail patients, geriatric, surgical oncology

Outcome measures

Primary outcome

Main study parameters/endpoints: The main endpoint is the cumulative incidence of delirium (measured with the Delirium Observation Scale and the DSM IV criteria) up to 10 days postoperatively. Secondary endpoints are: returning to the pre-operative living situation within 3 months postoperatively,the Physical Component Summary measure (PCS) of the SF-36, the Mental Component Summary measure (MCS) of the SF-36, complications during hospital stay including mortality, care Dependence Scale at discharge. Direct health care and non-health care costs will be used as economic indicators

Secondary outcome

see above

Study description

Background summary

Rationale: It has been shown that a multicomponent intervention can decrease the occurrence of delirium in older patients (Inouye et al 1999). Geriatric liaison teams are well trained in implementing best-supportive care programs for elderly. In standard care geriatricians are not involved in pre-operative screening of patients and perioperative care and will only be consulted after major complications (delirium) or functional losses have occurred.

Study objective

Objective: The primary objective of this study is to show that early detection

of geriatric patients at risk of preventable functional decline following a surgical procedure under general anesthesia for a solid tumor, combined with a geriatric liaison intervention will decrease the occurrence of delirium and consequent morbidity and mortality, without an increase in costs.

Study design

Study design: This is a multicenter prospective randomized clinical trial.

Intervention

Intervention: The intervention entails participation of a geriatric nurse and geriatrician in the perioperative treatment of the oncogeriatric surgical patient.

Study burden and risks

The participating patients will have to complete 2 questionnaires at inclusion in the study which will take about 30 minutes in total. During their hospital stay they will be asked to complete several questionnaires which will take 15 minutes daily on average. Also 3 months postoperatively they will be asked to complete a questionnaire which takes 15-30 minutes on average. The Hb value will be taken from the routine blood samples and no extra blood samples or diagnostic tests will be performed on the participating patients unless their medical condition requires this (e.g. to rule out dehydration). Although changes in diet or medication may be made in the study group these are not expected to cause an extra burden or discomfort to the participating patients. No experimental drugs will be used during 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

frail elderly patients in need for a cancer operation

Exclusion criteria

unable to comply outcome questionaires
no compiance for follow-up

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2007
Enrollment:	294
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL15136.042.06