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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21719

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: ZonMw, Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie
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Intervention

Outcome measures

Primary outcome

The cumulative incidence of delirium (measured with the Delirium Observation Scale and the DSM IV criteria) up to 10 days postoperatively.

Secondary outcome

1. Returning to the pre-operative living situation within 3 months postoperatively;

2. The Physical Component Summary measure (PCS) of the SF-36;
3. The Mental Component Summary measure (MCS) of the SF-36;
4. Complications during hospital stay including mortality;
5. Care Dependence Scale at discharge;
6. Direct health care and non-health care costs will be used as economic indicators.

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.
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: This is a multicenter prospective randomized clinical trial.
Study population: Patients over 65 years of age admitted to the Department of Surgery of the participating centres for the surgical or combined cancer treatment (surgery / radiation /chemotherapy / hormonal therapy) of a solid tumor will be included in this study
Intervention: The intervention entails participation of a geriatric nurse and geriatrician in the perioperative treatment of the oncogeriatric surgical patient.
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
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study 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.

Intervention

The intervention entails participation of a geriatric nurse and geriatrician in the perioperative treatment of the oncogeriatric surgical patient. Multi-component interventions to achieve best-supportive care in individual treatment plans will be implemented. These will be focused on electrolyte- and fluid levels, pain management, pharmacological clearance, miction and defecation, nutrition, early mobilization and rehabilitation, sleep, vision, hearing and cognition.The Delirium observation scale (DOS) will be used to screen for delirium by the nurse and the Delirium Rating Scale (DRS) will be used to measure the severity of the delirium (Trzepazc 1998, 2001). To ensure uniformity of geriatric intervention in participating centres a daily checklist will be used.

Contacts

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Eligibility criteria

Inclusion criteria

1. A score greater than 3 on the Groningen Frailty Index (GFI);

2. Surgery is scheduled more than 24 hours after inclusion in the study as we feel this is the time necessary for the geriatric team to plan their perioperative measures;
3. Surgery under general anesthesia;
4. Written informed consent given according to local regulations.

Exclusion criteria

1. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule;
2. Patient unable to comply with the outcome questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

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

Ethics review

Positive opinion

Date:	21-11-2006
Application type:	First submission

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
NTR-new	NL810
NTR-old	NTR823
Other	: N/A
ISRCTN	ISRCTN46161863

Study results

Summary results
N/A