Predicting postoperative outcome in elderly surgical cancer patients. Biomarkers and handgrip strength as predictors of postoperative outcome in elderly

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26102

Source
NTR

Brief title
PICNIC BHAPPY

Health condition

Older adults, postoperative cognitive decline, functional decline, inflammatory response, onco-geriatric patients, surgery

Sponsors and support

Primary sponsor: University of Groningen
Source(s) of monetary or material Support: University of Groningen

Intervention

Outcome measures

Primary outcome

A change in cognitive functioning at two weeks, three months and one year postoperatively as measured by the Ruff Figural Fluency Test, Trailmaking Test and Rey's verbal learning test in comparison to the preoperative scores.

Secondary outcome

- postoperative delirium

- postoperative complications

- one year mortality

- physical performance status

- quality of life

Study description

Background summary

Onco-geriatric surgical patients are at an increased risk of postoperative complications. Especially postoperative cognitive impairment has an enormous impact on quality of life and daily functioning in this population.

An inflammatory response to surgery seems to be related to the development of postoperative cognitive decline, delirium and other postoperative complications.

The aim of this study is to investigate the effects of this inflammatory response and identify predictors and possible confounders like preoperative inflammation level, muscle strength, nutritional status and general functioning on this effect.

Study objective

The effects of the inflammatory response to a surgical procedure on postoperative cognitive decline in elderly cancer patients will be investigated. Preoperative inflammation level, muscle strength, nutritional status and general functioning will be investigated as possible confounders of postoperative impairment.

Study design

preoperatively, at hospital discharge or two weeks postoperatively and three months and one year postoperatively

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• surgery is scheduled more than 24 hours after inclusion in the study as we feel this is the time necessary to obtain test results and plan the intraoperative recording of data.

• surgery under general, local or regional anaesthesia.

• written informed consent given according to local regulations.

• Patients can only be included in this trial once.

Exclusion criteria

• any physical condition potentially hampering compliance with the study protocol and

follow-up schedule, this includes: severe visual impairment, total deafness or the inability to hold a pencil

• personal time constraints unabling patients to comply to the study protocol

• patients unable to comply with the outcome questionnaires (this includes insufficient knowledge of the Dutch language)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	672
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-01-2014
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	NL4441
NTR-old	NTR4564
Other	: METc2014/095

Study results

Summary results
None