Postoperative cognitive dysfunction in elderly cancer patients

Published: 28-05-2010
Last updated: 02-05-2024

In this pilot study experience will be obtained in diagnosing POCD and its risk factors, in elderly surgical cancer patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34981

Source
ToetsingOnline

Brief title
POCD in elderly

Condition

- Procedural related injuries and complications NEC
- Gastrointestinal therapeutic procedures

Synonym
cognitive dysfunction, memory and attention

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: persoonsgebonden budget van de faculteit besteed door verantwoordelijke onderzoeker

Intervention

Keyword: Cancer, Cognitive, Elderly, Surgery

Outcome measures

Primary outcome

The incidence of POCD defined by a postoperative change in cognitive function measured by the Ruff Figural Fluency (RFFT) score and Trailmaking test (TMT) score in comparison to the preoperatieve score. Secondary outcome measures are

Secondary outcome

memory (measured by the 15 words test) and daily functioning and quality of life measured by the instruments in the "minimale dataset (MDS)". These tests will be performed preoperatively and at discharge (or a maximum of 2 weeks postoperatively) and 3 months postoperatively.

Study description

Background summary

Postoperative cognitive dysfunction (POCD) is a phenomenon that has an enormous impact on the ability of elderly patients to function independently in everyday life. In contrast to what is generally believed, the knowledge on the incidence and impact of POCD on quality of life is very limited. It is therefore of the utmost importance to establish the incidence of POCD including its predictors.

Study objective

In this pilot study experience will be obtained in diagnosing POCD and its risk factors, in elderly surgical cancer patients.

Study design

Observational study

Study burden and risks

The participating patients will have to complete 3 tests and 2 questionnaires at inclusion in the study which will take about 60 minutes in total. At discharge and 3 months postoperatively they will be asked to complete the same set of tests and questionnaires. Blood and saliva samples will be taken preoperatively and postoperatively to determine operative immuneresponse measured by Interleukine-6 (Il-6) blood levels, and peroperative stress measured by cortisol levels in saliva . A reference blood sample will be stored for future analysis. These blood samples or the tests they are asked to complete 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

Patients over 65 years of age admitted to the Department of Surgery of the University Center Groningen for the surgical or combined cancer treatment (surgery / radiation /chemotherapy / hormonal therapy) of a solid tumor will be included in this study. This will include patients undergoing surgery for a malignancy of the breast, thyroid, soft tissue, hepatobilliairy tract, colorectal tumors, and skin tumors• 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 anesthesia.
• written informed consent given according to local regulations

Exclusion criteria

• any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.;• patient unable to comply with the outcome questionnaires

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	28-05-2010
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	NL31486.042.10