Randomized Clinical Trial on peri-operative interventions for fragile older patients undergoing surgery. The Profyd trial.

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The objective of the study is to improve the peri-operative care for fragile older patients who have been indicated for elective surgery of thorax and abdomen.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38365

Source
ToetsingOnline

Brief title
Better in / Better out

Condition

- Other condition

Synonym
faster return to home, optimal interdisciplinary collaboration

Health condition

preventie van complicaties en functionele achteruitgang na electieve thorax- en buikchirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: ZonMw (Nationaal Programma Ouderenzorg)

Intervention

Keyword: fragility, multimorbidity, post-operative complications

Outcome measures

Primary outcome

The primary outcome measures are complications after surgery and the length of

stay in the hospital.

Secondary outcome

The secondary outcome measures are participation, quality of life, activities

of daily life and the nutritional status.

Study description

Background summary

Hospital admission can be a major life event for fragile older people, associated with increased morbidity and mortality. Especially, large invasive surgical interventions are in elderly patients increasingly accompanied with complications, delirium, loss of function and mortality. To decease post-surgical complications in fragile older patients indicated for elective surgery small pilot studies have been conducted, which were mainly monodisciplinary interventions. The effectiveness of a combination of pre-surgical screening for multiple risk factors, followed by pre- and post-surgical interventions in the 1st and 2nd line adjusted to the patient*s status has rarely been investigated.

Study objective

The objective of the study is to improve the peri-operative care for fragile older patients who have been indicated for elective surgery of thorax and

abdomen.

Study design

A single blinded Randomized Controlled Trial (RCT) investigating the effects of two interventions. The patients undergoing one of the two interventions are unaware of the intervention given to them.

Intervention

The intervention group starts immediately with pre-surgical interventions adjusted to the patients* status. Daily activities and the patient*s fitness level are trained by a physiotherapist, the patients nutritional status will be improved by a dietitian, risk factors for a delirium are minimized and medication will be minimized as much as possible by a geriatrician. These interventions will be continued when needed (clinical and post-clinical in the 1st or 3rd line). Patients in the control group will receive the usual peri-operative care.

Study burden and risks

A screening takes place to determine whether participants are suitable for the study. By means of the VMS it is checked whether the elderly person meets the four criteria for fragile elderly people: delirium, falls, malnutrition and physical constrains.

Measurements during the investigation
There will be four measurements; a baseline measurement after the screening when the patient agrees to participate in this study, shortly before surgery when the patient is hospitalized, 1 month and 6 months after surgery.
The participants will be asked to complete questionnaires and two physical tests will be carried out. An extensive description of the questionnaires and the tests is given in chapter 6 of the research protocol, the C1 document.

Intervention group
Participants in the intervention group will be visited by a physiotherapist and a dietitian conform the course that was given. Patients will also meet with a geriatrician who will try to diminish the risk factors for a delirium and will try to minimize the amount of medication used. Treatment by the physiotherapist, dietarian and geriatrician will be continued in the hospital during hospitalization. After the patient*s discharge from the hospital and when needed, treatment by a physiotherapist and dietitian will be continued for a maximum of four weeks. Treatment by a geriatrician will be continued, when needed, for a maximum of four weeks as well.

Control group

The participants in the control group receive the care as usual.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elderly with an age above 70 years
The elderly person lives independently or in an assisted living
The erderly person undergoes an elective curative operation of abdomen/ thorax, during which the abdomen/ thorax is opened.
They have to be vulnerable on at least 1 of the 4 criteria; delirium, number of falls, malnutrition and physical constraints.
They have to live close to the hospital.;See document C1 Researchprotocol chapter 4.2 on page 14

Exclusion criteria

Severe dementia (Clinical Dementia Rating >=2)
Unsufficient understanding of the Dutch language to be able to understand instructions. This holds true for the patient him-/herself but also for the caregiver.;See document C1 Researchprotocol chapter 4.3

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	29-06-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL35514.060.11