

Optimalisation Elderly pathway pre operative

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON42382

Source

ToetsingOnline

Brief title

OUTO

Condition

- Deliria (incl confusion)
- Gastrointestinal therapeutic procedures

Synonym

Delier / confusion, intestinal cancer and Abdominal aortic aneurysm

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis, Breda

Source(s) of monetary or material Support: [unrestricted grant] by Amphia Fund for Innovation ; Vifor Pharma sponsor

Intervention

Keyword: delirium, Elderly, optimisation, surgery

Outcome measures

Primary outcome

Our main outcome is the incidence of delirium measured by DOS scores, it's duration and severity.

Also the mortality within one year.

Secondary outcome

Secondary we will investigate post operative complications and length of hospital stay.

Pre operative Factors of frailty will be analysed, age, gender, co morbidity, surgical history, medication use, home situation.

per-operative characteristics e.g. kind of anesthesia, duration of surgery, complications during surgery, bloodloss.

post operative characteristics e.g. ICU admission, duration ICU and complications.

Study description

Background summary

The population of people above 65 years old is expected to double in the next 35 years. The increase of age is associated with an increase in need for medical care and number of patients requiring surgery. A higher rate of post operative complications, like a delirium (37%), longer hospital stay, ICU admission, and mortality is associated with increasing age.

In our hospital, within the population of 70 years or older, approximately 85 patients per year undergo surgery for colorectal cancer and about 50 patients a year undergo surgery for abdominal aortic aneurysm. We expect an increase in

the number these surgical procedures performed during the coming years (also due to the implementation of screening programs).

A delirium is often a fatal disorder, which affects as much as 50 % of the elderly people who are hospitalised. In this population, as described above, the incidence of a delirium is about 15%. The 6-month mortality is increased within patients with a postoperative delirium (20%) versus no delirium (3%). [3]

In short a delirium is a common complication after surgical intervention and results in a significant decrease in quality of life, an increased rate of complications, mortality and additionally is associated with high costs. Therefore a delirium holds essential health relevance.

Our goal is to anticipate on these factors of frailty in an early phase of care, instead of at admission and to optimise patients during 5 weeks before surgery, so less delirium, complications, hospital stay and mortality will occur.

Study objective

Our primary aim is to tackle the factors of frailty in an early phase, which is possible in elective planned surgery. We hypothesise that optimal preparation, starting 5 weeks before surgery, will reduce the incidence of delirium from 15 % to 7.5 %.

Our secondary aim is to reduce post-operative complications, hospital stay, and 6 months mortality.

Study design

This study will be a prospective interventional study, (Intention to treat) starting first of January 2016, till January 2018.

A clinical pathway is set up for all patients of seventy years or older with surgical indication for colorectal cancer or abdominal aortic aneurysm, the 70PLUS outpatient clinic in our surgery department. Within one week after confirming the indication for surgery, a nurse practitioner, a physiotherapist and a dietician will see these patients and all factors of frailty will be investigated. If needed, a geriatrician will also see the patient for complete geriatric assessment and advice during admission to prevent delirium. Diet advice and physical exercises will be given to all patients in need. Patients must follow these advices and keep a diary.

Intervention

This study is set up as an outpatient clinical pathway in which we intervene in

the usual pathway till operation. Within one week after confirming the indication for surgery patients will be seen. All factors of frailty will be investigated. Questionnaires will be taken and physiotherapist will improve patients physical condition, if needed refeeding or dietary advice will be given. If needed a geriatrician will be consulted. If patient is anaemic iron injection will be given.

factors that will be assessed and treated are:

1. dietician advice and/or refeeding
2. anaemia
3. physical condition
4. home evaluation for postoperative care
5. screening and prevention for delirium
6. quality of life

Study burden and risks

A clinical pathway is set up for all patient of 70 or older with surgical indication for either colorectal cancer or abdominal aortic aneurysm, the 70 PLUS outpatient clinic in our surgery department. At the outpatient clinical pathway (T1) we will assess all base line patient characteristics and questionnaires will be taken. All patients will visit the physiotherapist, to assess patients* condition. If needed dietician will be consulted or geriatrician. A total of 3 hours (including consultation of dietician and geriatrician) is needed for each patient.

If needed (in case this is not done during work up) blood is drawn for baseline results, to assess anaemia, nutritional status and renal function.

At hospital admission (T2) patients will be seen by the same physiotherapist. Also the same lab results will be measured.

At discharge (T3) patients will fill in questionnaires and blood will be drawn.

At follow up after six months (T4) and 12 months (T5) questionnaires will be taken.

In total we anticipated about 5 hours of extra time needed next to usual care given.

Due to i.v. Iron injection , allergic reaction can occur. This product is used normally for anaemic patients with iron deficiency. In-hospital protocol is already in use and no other or adjuvant extra care will be undertaken. Addendum describes the in-hospital protocol for the use of i.v. iron injection.

Due to physical exercises patient can fall. Usual care will be given.

We anticipated that no other risk is associated with participation.

Contacts

Public

Amphia Ziekenhuis, Breda

Molengracht 21

Breda 4818 CK

NL

Scientific

Amphia Ziekenhuis, Breda

Molengracht 21

Breda 4818 CK

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patient must be 70 years of age or older

Primary abdominal surgical intervention due to colorectal cancer or abdominal aneurysm

Exclusion criteria

Patients who are operated on within one year after earlier abdominal surgery

Patient with dementia or not capable to fill in a questionnaire (e.g. language barrier)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2015
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO	
Date:	11-04-2016
Application type:	First submission
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

ID: 23625
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL55694.101.15
OMON	NL-OMON25815
OMON	NL-OMON23625