OUTO study

No registrations found.

Ethical review Positive opinion

Status Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON23625

Source

Nationaal Trial Register

Brief title

OUTO

Health condition

Colorectal cancer, abdominal aortic aneurysm

Sponsors and support

Primary sponsor: L. van der Laan, MD PhD, Department of Surgery, Amphia hospital Breda, The Netherlands.

Source(s) of monetary or material Support: Vifor Pharma = Initiator = Sponsor

Intervention

Outcome measures

Primary outcome

Incidence of delirium

Secondary outcome

Complications, length of hospital stay, ICU admission, functional dependency, institutionalision, qualtity of life and mortality up to one year

Study description

Background summary

Before-and-after trial on the effectiveness of a prehabilitation program to reduce the incidence of postoperative delirium and other postoperative adverse events

Study objective

Multicomponent prehabilition can reduce postoperative delirium and other postoperative adverse events

Study design

Baseline, discharge, 2 weeks post-discharge, 6 months and 12 months

Intervention

For an optimal period of 5 weeks prior to surgery, physical health, nutritional health status, factors of frailty and haemoglobin levels will be optimised

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Patients aged 70 years or older;

All Ethnicities;

Both sexes:

Patients planned to undergo elective abdominal surgery for colorectal cancer or an abdominal aortic aneurysm;

Exclusion criteria

Acute admission or surgical intervention, All patients who do not speak Dutch or English.

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-11-2015

Enrollment: 267

Type: Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date: 05-04-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42382

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL5575 NTR-old NTR5932

CCMO NL55694.101.15
OMON NL-OMON42382

Study results