Detection of hypovolemia in the elderly patient undergoing surgery

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The primary aim of the study is to determine the incidence of perioperative hypovolemia in the elderly patient scheduled for major surgery, and how this relates to postoperative complications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48868

Source
ToetsingOnline

Brief title
The HOOI study

Condition

- Other condition
- Electrolyte and fluid balance conditions
- Decreased and nonspecific blood pressure disorders and shock

Synonym
dehydration, low circulatory volume

Health condition

veroudering (fysiologisch)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aged, hypovolemia, perioperative, surgical procedures

Outcome measures

Primary outcome

Incidence of hypovolemia: percentage of patients that have a change in stroke

volume of more than 10% upon a passive leg raising test, per time point.

Secondary outcome

The relationele of hypovolemia with postoperatieve complications; delirium and

acute kidney injury.

Study description

Background summary

Elderly patients are vulnerable voor hypovolemia; they have a reduced fluid intake resulting from an reduced sense of thirst, physiological diastolic myocardial dysfunction and a reduced response to catecholamine. Added tot his, there is frequent polypharmacy and multiple comorbiditeit. This makes elderly patients strongly preload dependent when an increase in cardiac output is needed. Hypovolemia leads to diminished preload causing failure of the cardiac output. Hypovolemia can therefore lead to inadequate organ perfusion, increasing the risk of postoperative complications such as delirium, surgical site infection and acute kidney injury. While an hypovolemic state kan easily be treated by means of optimizing circulatory volume.

There is currently limited evidence available on the occurrence of perioperative hypovolemia in the elderly population, and whether this hypovolemic state is related to postoperative complications in these patients. More information regarding this relationship may be valuable in strategies aiming for a reduction in postoperative complications in the elderly. In particular, postoperative complications lead to long term morbidity, decrease

quality of live, increase costs and are the most important factor of patient survival. In the present study we therefore aim to investigate how many elderly patients suffer from hypovolemia in the perioperative period, and how this relates to postoperative complications.

Study objective

The primary aim of the study is to determine the incidence of perioperative hypovolemia in the elderly patient scheduled for major surgery, and how this relates to postoperative complications.

Study design

At four time points (preoperatively, postoperatively, after 24h and after 48h) de volemic status will be assessed for the presence of hypovolemia.

Hypovolemia is defined as the presence of fluid responsiveness, measured as an increase in stroke volume of 10% or more with the Nexfin, 1-5 minutes after conducting a passive leg raise.

A passive leg raise is a maneuver in which the cardiac output measurement will be performed first in sitting position, and then will be repeated after lowering the head end of the bed en lifting the legs 30 degrees.

The Nexfin apparatus is a frequent used non invasive method to assess the cardiac output with use of counterpulsations in a cuff placed around a finger.

Study burden and risks

One of the investigators will visit the ward and will use the inflatable blood pressure cuff around the index finger of the right hand. The measurement will be performed while sitting, and is continued for 5 minutes after lowering the head end of the bed and raising the lower end of the bed. As the bed works electronical the change in movement occurs slowly and will not cost any effort. Overall discomfort associated with these tests is regarded to as minimal. There are no benefits related with participation.

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

* Informed consent
* Age 70 years or older
* Scheduled for major surgery, defined as an expected length of stay of at least two postoperative days.
* Patients who are fully able to understand the information letter

Exclusion criteria

* Patients with cardiac arrhythmias
* Symptoms of cardiovascular shock or decompensation at presentation
* Impossible to perform measurements due to patient characteristics
* Procedure in ambulatory practice
* Acute surgery

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):	01-05-2018
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Nexfin
Registration:	No

Ethics review

Approved WMO

Date:	18-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	08-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62141.029.17