INFLAMMATION IN ATHEROSCLEROTIC PLAQUES: ENHANCED BY MAJOR SURGERY OR SEPSIS?

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With this study we will evaluate the following hypothesis: Does acute systemic inflammation induces plaque instability and could it be repsonsible for the elevated risk of cardiovascular events. Eventually this study can contribute to the knowledge...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON44649

Source
ToetsingOnline

Brief title
Effect of surgery or pneumonia on atherosclerosis

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, hardening of the arteries

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ICaR VU

Intervention

Keyword: atherosclerosis, inflammation, pneumonia, surgery

Outcome measures

Primary outcome

FDG-tracer uptake in the vessel wall

Secondary outcome

Markers of systemic inflammation in the blood

Study description

Background summary

Observational studies confirm that the risk for cardiovasculair events is elevated in the weeks after conditons of systemic inflammation, such as majeur orthopedic surgery and sepsis. It is unknown what is the reason for this attributed risk, athough It has been suggested that inflammation enhances atherosclerosis.

Study objective

With this study we will evaluate the following hypothesis: Does acute systemic inflammation induces plaque instability and could it be repsonsible for the elevated risk of cardiovascular events. Eventually this study can contribute to the knowledge of infarction and stroke and could help to reduce the incidence.

Study design

To eveluate the effect of pneumonia and major surgery on atherosclerosis we perform scans of the vessels. We compare trace uptake in the atherosclerotic plaques during a periode of systemic inflammation and during a periode without systemic inflammation.

Study burden and risks

The risk is considered intermediate. There is a small change of a severe complications: malignant tumor as a consequence of the radiation

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

Admitted for pneumonia or being scheduled for total knee replacement or total hip replacement.
A calculated 10 years risk of fatal cardiovascular disease of >= 10 % in the SCORE table
Age > 50 years

Exclusion criteria

Unable to remain supine for at least 60 minutes
Pneumonia patients being too ill, as considered by the treating physician

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-10-2017
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	NL54345.029.15