Ultra low-dose chest ct with iterative reconstructions as an alternative to conventional chest x-ray prior to heart surgery

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To assess if information about aortic calcification obtained from routine preoperative ultra low-dose chest CT reconstructed with IR lowers the postoperative stroke rate in patients undergoing heart surgery by optimizing surgical strategy compared...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON45046

Source ToetsingOnline

Brief title CRICKET study

Condition

- Cardiac disorders, signs and symptoms NEC
- Central nervous system vascular disorders

Synonym CVA, stroke

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** ZonMw

Intervention

Keyword: aortic calcification, Chest CT, Heart surgery, iterative reconstruction

Outcome measures

Primary outcome

- Percentage of patients suffering from in-hospital postoperative stroke

(central neurological defect that either recovers spontaneously or is

permanent) after heart surgery.

Secondary outcome

- Percentage of patients in which the surgical approach is altered based on

information derived from the preoperative chest CT.

Study description

Background summary

During heart surgery the aorta is clamped to initiate cardiopulmonary bypass. This may crush aortic calcifications causing them to embolize to the brain causing a stroke

which is a devastating complication for the patient. A chest X-ray is routinely performed prior to heart surgery. It provides no information about aortic calcification. Imaging by a chest computed tomography (CT) scan provides detailed information on aortic calcification but has higher radiation exposure and thus is not used routinely. Recently iterative reconstruction (IR) techniques have become available that allow chest CT to be performed at markedly reduced dose with retained image quality. Routine use of low dose chest CT with IR prior to heart surgery may identify patients with a severely calcified aorta in which the surgery may subsequently adapted to minimize or avoid aortic manipulation which may reduce stroke rate.

Study objective

To assess if information about aortic calcification obtained from routine preoperative ultra low-dose chest CT reconstructed with IR lowers the postoperative stroke rate in patients undergoing heart surgery by optimizing surgical strategy compared to the normal work-up with a conventional chest X-ray.

Study design

Multicenter randomized controlled trial.

Study burden and risks

For research purposes an additional low-dose CT-scan of the chest is performed in the *intervention* group. This scan will require approximately 5 minutes in total (including patient preparation). The additional radiation dose for patients in the intervention group will be less than 1 mSv. Because the low-dose scans are non-contrast enhanced there is no additional risk due to use of contrast agents. Patients in the control group will have to do nothing expect sign informed consent.

Patients in the intervention group may benefit directly from participating in this study (better planning of surgery, potential of less risk of calcific emboli to the brain). Patients in the control group do not benefit directly from participating in this study.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- 18 years old or older
- Scheduled to undergo heart surgery
- Provide written informed consent

Exclusion criteria

- Patient not meeting inclusion criteria
- Pregnant women
- Scheduled to undergo transcatheter aortic valve insertion procedure
- Patients that underwent a chest CT in the past three months
- Emergency surgery

- Concomitant or previous participation in a study that prohibits the patient from participating in a study that exposed the patient to radiation

- Unwillingness to be informed about unrequested findings on the CT scan

Study design

Design

Study type:Observational invasiveIntervention model:ParallelAllocation:Randomized controlled trialMasking:Open (masking not used)Primary purpose: Diagnostic

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Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2014
Enrollment:	1724
Туре:	Actual

Ethics review

Approved WMO	
Date:	10-04-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	28-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 26609 Source: NTR Title:

In other registers

Register	ID
ССМО	NL47293.041.13
OMON	NL-OMON26609

Study results

Results posted:

08-03-2022

First publication 16-11-2021