

Lage dosis CT scan voor een hartoperatie

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26609

Bron

Nationaal Trial Register

Verkorte titel

CRICKET studie

Aandoening

heart surgery, complications, computed tomography, stroke, aortic calcifications, iterative reconstruction

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative in hospital stroke rate

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

After completion of inclusion, all data will be analyzed.

Onderzoeksproduct en/of interventie

Patients are randomized to 2 groups: the intervention group undergoes an ultra low-dose non-contrast enhanced chest CT with IR in addition to routine care. The control group undergoes routine care (which includes a chest X-ray).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patient not meeting inclusion criteria
- Pregnant women
- Scheduled to undergo transcatheter aortic valve insertion procedure (since these patients receive a standard preoperative CT)
- 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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Parallel

Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	1724
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45046
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4336
NTR-old	NTR4533
CCMO	NL47293.041.13
OMON	NL-OMON45046

Resultaten

Samenvatting resultaten

J Cardiovasc Comput Tomogr. 2016 Jan 30. pii: S1934-5925(16)30015-6. doi: 10.1016/j.jcct.2016.01.016. [Epub ahead of print]

Ultra low-dose chest ct with iterative reconstructions as an alternative to conventional chest x-ray prior to heart surgery (CRICKET study): Rationale and design of a multicenter randomized trial.

den Harder AM1, de Heer LM2, Maurovich-Horvat P3, Merkely B3, de Jong PA4, Das M5, de Wit GA6, Leiner T4, Budde RP7.

<http://www.ncbi.nlm.nih.gov/pubmed/26857421>