Multislice computed tomography coronary angiography in patients with stable and unstable angina: a multicenter study.

Gepubliceerd: 08-09-2005 Laatst bijgewerkt: 13-12-2022

Is diagnostic non-invasive coronary angiography with MS-CT a cost-effective alternative to diagnostic invasive coronary angiography in the management of patients with stable and unstable angina pectoris, referred for evaluation of the presence of...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20510

Bron
NTR

Verkorte titel
N/A

Ondersteuning

Primaire sponsor: ZonMw NL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic accuracy in terms of sensitivity, specificity and predictive value of MS-CT to detect significant obstructive coronary lesions (>50% lumenal diameter reduction with QCA) using the diagnostic invasive coronary angiogram as the reference standard.
The costs,

effectiveness, and the cost-effectiveness of non-invasive MS-CT coronary angiography as an initial test will be compared to diagnostic invasive coronary angiography.

Toelichting onderzoek

Achtergrond van het onderzoek

The study is a prospective multicenter non-randomized study. Three centers will be involved of which 2 centers are University Hospitals
1) Erasmus Medical Center and
2) Utrecht Medical Center and one affiliated teaching hospital: Antonius Ziekenhuis Nieuwegein.
The Erasmus MC will enroll 60 stable and 60 unstable patients while the other two participating center will enroll 50-60 stable and 50-60 unstable patients.

All patients will first undergo a non-invasive MS-CT coronary angiogram. The outcome of the MS-CT scan in terms of presence and location of significant coronary obstruction(s) will be separately assessed by 2 investigators (1 cardiologist, 1 radiologist) unaware of the outcome of the subsequent diagnostic angiogram. In case of disagreement consensus will be achieved by a third reader.

All patients, independent of the outcome of the scan, will be scheduled for diagnostic coronary angiography. The diagnostic coronary angiogram will be separately assessed by two cardiologists, unaware of the outcome of the MS-CT scan.
Quantification of coronary stenoses will be performed using automated contour detection algorithms (QCA).

Doel van het onderzoek

Is diagnostic non-invasive coronary angiography with MS-CT a cost-effective alternative to diagnostic invasive coronary angiography in the management of patients with stable and unstable angina pectoris, referred for evaluation of the presence of significant coronary obstructions to determine further treatment strategies consisting of medical treatment, or revascularization (percutaneous coronary intervention or coronary bypass surgery).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

MS-CT coronary angiography: An MS-CT coronary angiogram is performed using a bolus injection of 100 ml contrast agent into a brachial vein.
The scan is made during a breathhold of 20 seconds.

The whole procedure, including patient instruction, preparation and data acquisition requires about 10-15 minutes.
The scan is performed by a technician under supervision of a cardiologist or radiologist. Postprocessing and reading of the images requires another 10-20 minutes which is done off-line by a cardiologist and radiologist.

It is expected that faster post-processing tools will become available which will significantly reduce MS-CT reading time. A Siemens 16 slice MS-CT (EMC, Rotterdam)and a Philips 16-slice MS-CT (UMC, Utrecht; Antonius Hospital Nieuwegein).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Symptomatic patients with stable angina (N=160) and unstable angina (N=160) who are scheduled for diagnostic invasive coronary angiography will be enrolled into the study.
In addition these patients also need to fulfill the following inclusion criteria.
a) male and female younger than 70 years,

b) stable angina pectoris that warrants further evaluation by coronary angiography and revascularization by percutaneous coronary intervention,
c) stable heart rhythm,
d) heart rate less than 70 b.p.m. (either spontaneous or drug-induced) and
e) no contra indications such as severe renal or pulmonary dysfunction or X-ray contrast intolerance.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients will be excluded if they are:

1. Older than 70 years; and

2. Have an irregular heart rhythm (predominantly atrial fibrillation); or

3. Have severe renal or pulmonary dysfunction or x-ray contrast intolerance.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-11-2004
Aantal proefpersonen:	320
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL450
NTR-old	NTR490
Ander register	ZonMW : 945-04-263
ISRCTN	ISRCTN43894092

Resultaten

Samenvatting resultaten
N/A