Additional value of 3D rotation coronary angiography with the Allura 3D-CA system versus conventional coronary angiography. The COROTA trial.

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- Comparing the interpretation of the coronary system with the conventional used projections (golden standard) versus the rotational projection and the reconstructed 3D-coronary model. -Comparing the used amount of contrast fluid and radiation dose...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON31002

Source
ToetsingOnline

Brief title
COROTA- trial

Condition

- Coronary artery disorders

Synonym
atherosclerosis, coronary disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Intervention

Keyword: 3D, coronary angiography, coronary stenosis, rotation

Outcome measures

Primary outcome

- Qualitative and quantitative scoring for coronary stenosis (severity and numbers), coronary anatomy (left- or right system dominance; separate ostia LAD/CX; other coronary anomalies), TIMI-flow, thrombus, dissection and calcification. Qualitative stenosis scoring wil take place in the conventional projectings of the RCA and LCA and in the rotation projections of the RCA and LCA. The quantitative stenosis scooring will be performed with QCA software (quantitative coronary angiogram) on the conventional projections, the rotation images and with the Allura system on the created 3D coronairy model.

-After the diagnostic coronary procedure, the obtained projections of the conventional projection, the rotation projection and the 3D reconstruction model are independently scored by 2 interventional cardiologists.

-Patient characteristics and the obtained data from the coronary projections are analyzed in a database.

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Secondary outcome

- Comparison will take place fore possible variations in used x-ray contrast fluid and radiation dose at the different projection techniques.

Study description

Background summary

Coronary angiography is one of the most commonly performed invasive diagnostic procedures in the world. During a coronary angiography (CAG) there are multiple projections performed of the coronary artery with the aim of optimal determination of the coronary-lumen during screening for potential coronary stenosis. The number op the performed projections of the coronary system vary per cardiologist and center. Although generally speaking for a good coronary determination, there are ad least 2 projections of the right coronary system and 5 projections of the left coronary -system required. At the presens of a coronary stenosis, there may be additional projections required for a good determination of the severity and aspect of the stenosis. This because one as to look for the optimal projection angle for the involving coronary artery.
For each coronary projection, X-ray contrast injection is being used (Xenetix or Hexabrix). These x-ray contrast fluids are potential nefrotoxisch. It is therefore important to inject as minimum as possible of these x-ray contrast fluids. At each coronary projection, the patient and medical staff are also exposed to x-ray radiation. It therefore needs no further explanation that the more coronary projections are being made, the more exposure to potential harmful x-ray contrast fluid en radiation.
With new software techniques one is searching for possibilities to get the optimal coronary imaging interpretation with the minimum amount op projections. The Allura 3D-CA is a software system of Philips with some advanced possibilities for diagnostic and interventional cardiology. The system has the possibility to create a 3 dimensional presentation of the coronary arteries. It also can improve the understanding of the coronary system bij creating a 3D model of the coronary system. From there an optimal 2D working viewing angle is provided for coronary interventions. The Allura 3D-CA system therefore performs a so called coronary rotation projection from LAO 55 to RAO 55 (= 110 degr of rotation), this rotation is made in 25 degrees cranial angulation. One rotation projection takes 4 seconds and contrastfluid needed per run will probably be around 10-12cc for LCA and 8-10cc for RCA. (Xenetix or Hexabrix). However there is no data if the rotational angiografy makes an even good interpretation of coronary stenoses possible as the conventional angiography.

Study objective

- Comparing the interpretation of the coronary system with the conventional used projections (golden standard) versus the rotational projection and the reconstructed 3D-coronary model.
-Comparing the used amount of contrast fluid and radiation dose between the conventional- and the rotation projections.
-There also will take a quantitative interpretation comparison place. For this a QCA (quantitative coronary angiogram) will be performed at the conventional

projections and compared with the quantitative stenosis scoring on the 3D-reconstruction model on the Allura system.

Study design

A total of 60 patients suspected for coronary artery disease which therefore have to undergo a diagnostic coronary angiogram. A written informed consent obtained. Renal functions before the procedure will be estimated by calculating the kreatinine clearence and glomerular filtration rate (GFR), according to the Cockroff-Gault formula before and where possible 24 hours after the procedure. Patients who meet the following criteria should be excluded: age < 18 years, kreatinine clearance <90 ml/min/1.73m2, presens of coronary bypassgrafts, haemodynamic instability / emergency setting. The coronary angiogram (CAG) is being performed by a cardiologist in trainee with at least the experience of 50 performed CAG under supervision of a interventional cardiologist. In the absence of the cardiologist in trainee (or to inexperienced), the procedure is performed by a interventional cardiologist. The CAG is performed by the Judkins-technique. First two conventional projections are performed of the RCA (right coronary artery). In the RAO and LAO projection. After the conventional projections, an additional rotation projection is performed of the RCA from LAO 55 to RAO 55 (= 110 degr of rotation), this rotation is made in 25 degrees cranial angulation. After the projections of the RCA, the conventional projections of the LCA are performed. Usually there are 5 conventional projections of the LCA made from different angles. The decision for possible extra conventional projections is made by the supervising interventional cardiologist during the examination. Additional to the conventional projections, a rotation projection of de LCA will be performed. The rotation projection covers from LAO 55 to RAO 55 (= 110 degr of rotation), this rotation is made in 25 degrees cranial angulation.

During the procedure the used amount of x-ray contrast fluid and radiation dose are separately registered for the conventional and the rotation projections. The radiation dose used to determine the table height for the concerning projection are registered with the total radiation dose for that specific projection.

After the diagnostic coronary procedure, the obtained projections of the conventional projection, the rotation projection and the 3D reconstruction model are independently scored by 2 interventional cardiologists. The coronary projections are scored for coronary stenosis (severity and numbers), coronary anatomy (left- or right system dominance; separate ostia LAD/CX; other coronary anomalies), TIMI-flow, thrombus, dissection and calcification. Stenosis scoring is performed for each coronary segment (17 segments in total).There will also be quantitative stenosis scoring performed at the conventional projections and the 3D reconstruction model. Stenosis scoring (stenosis percentage and length) in the conventional projections is quantitatively measured by QCA software (quantitative coronary angiogram) for all 17 coronary segments. With the 3D-reconstruction model quantitative stenosis scoring is performed with the Allura 3D-CA system for each coronary segment. Patient characteristics and the

obtained data from the coronary projections are analyzed in a database. All scorings of the coronary segments obtained by the different projection methods are compared. Specific comparison will take pace fore possible variations in stenosis scoring, used x-ray contrast fluid and radiation dose at the different projection techniques.

Study burden and risks

Safety aspects

A coronary angiogram is a well established procedure and is a frequently used diagnostic procedure with patients suspected for coronary artery disease. Worldwide more than thousands of coronary angiograms are performed each month and makes it one of the most commonly performed invasive diagnostic procedure in the world. In our study only 2 extra rotation projections are performed during the CAG. These two extra projections involve additional 20 cc extra x-ray contrast fluid and 0,4 mSv radiation dose. Patients with pre-existing poor renal functions are excluded. This way we think that the total amount of used contrast fluid and radiation dose for the coronary angiogram is acceptable and still less than in most percutaneous coronary interventions.
Also there are no additional catheters intoduces during the procedure.
If the study-results reveal that rotation projections make a good coronary interpretation possible, this technique may save x-ray contrast fluid and radiation dose in the future as a possible replacement for the conventional coronary projections.

This study allows us to conclude if coronary rotation projections and 3D reconstruction models allow an even qualitative and quantitaive coronary interpretation compared with conventional projections. In addition, changes in contrast fluid and radiation dose between the different projection techniques may be detected.

Privacy aspects

All subjects have the right to see their own data and to discontinue the study, without consequences for their treatment.

Ethical aspects

All subjects will receive detailed verbal and written information - given by the investigator- concerning the nature, purpose and possible risks of the experiment, before they give their written informed consent.
This study proposal will be submitted to the Committee of Scientific Investigations in Humans (CMO = Commissie Mensgebonden Onderzoek Arnhem-Nijmegen) of this hospital for critical judgement and approval.

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

-Patients suspected for coronary artery disease or with an acute coronary syndrome and therefore have to undergo a diagnostic coronary angiogram.
-A written informed consent obtained.
-Renal functions will be estimated by calculating the kreatinine clearance and glomerular filtration rate (GFR), according to the Cockroff-Gault formula before the procedure and where possible 24 hours after the procedure. The astimated kreatinine clearance must be > 90ml/min/1.73m2.

Exclusion criteria

- age < 18 years

- kreatinine clearance, GFR < 90 ml/min/1,73m2
- presens of coronary bypassgrafts.
- haemodynamic instability / emergency setting.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL17732.091.07