Evaluating image quality in coronary angiography using diluted contrast agent

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The purpose of this study is to evaluate image quality by comparing images acquired using diluted contrast agent and adapted x-ray scan protocols to images of standard x-ray runs of a CAG procedure in the current clinical settings

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

Summary

ID

NL-OMON54640

Source
ToetsingOnline

Brief title
Diluted contrast in coronary angiography

Condition

- Coronary artery disorders

Synonym
coronary artery stenosis, narrowed coronary artery

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Aanvraag bij Philips-Isala research fonds zal worden gedaan.

Intervention

Keyword: coronary angiography, diluted contrast agent, X-ray dose variations

Outcome measures

Primary outcome

Primary endpoint: the mean image quality score of the research protocol, determined from a subjective judgement by cardiologists, is not lower by more than 0.2 points compared with the mean image quality score of clinical protocol (non-inferiority test). See section 3.3 of the protocol for the statistical analysis.

Secondary outcome

Secondary endpoint: the mean image quality score is computed off-site by measuring the CNR in a vessel in the research and reference runs. With the outcome of these measurements, the CNR will be correlated with the subjectively scored image quality. The objective is to determine the minimal required CNR.

Study description

Background summary

Cardiac procedures like coronary angiography (CAG) and percutaneous intervention (PCI) rely on the use of iodinated intravascular contrast for vessel and chamber imaging.
Contrast induced nephropathy (CIN) or contrast induced acute kidney injury (CI-AKI) occurs in 0-25% of patients undergoing CAG or PCI [1]. A subgroup of patients is at risk for this complication, depending of risk factors in which pre-procedure renal function is the most important. Outcomes for these patients may be severe; rehospitalisation, dialysis, renal replacement therapy and death. A reduction of administered iodine for these patients could lead to a reduction of complications associated with CI-AKI. Dilution of the contrast agent is a possibility to reach this reduction.

Study objective

The purpose of this study is to evaluate image quality by comparing images acquired using diluted contrast agent and adapted x-ray scan protocols to images of standard x-ray runs of a CAG procedure in the current clinical settings

Study design

We will perform a single center study, in which patient-x-ray runs obtained using different degrees of diluted contrast agents and adapted x-ray settings will be intra-individually compared.
Patient selection will be performed by Isala Heart Centre. Patients that meet the inclusion criteria, not excluded by the exclusion criteria and have signed informed consent will undergo a normal clinical CAG procedure. For the purpose of this study, three extra cine runs are performed with diluted contrast agent and adapted x-ray settings. There will be randomization for the side (left or right) for the four extra runs and for the order of the different research runs. One investigator will analyse the runs quantitatively, while three cardiologists will give qualitative (visual) judgments.

Study burden and risks

Additional amount of contrast agent
For the study, approximately 45 ml of contrast agent will be added to the amount of 120 ml on average (15 ml per run on average, in clinical routine eight runs are performed and three extra runs are performed for this study). Because of the dilution of the contrast agent, the iodine load for the patient raises with approximately 24% compared to the normal procedure.

The extra burden due to the contrast agents for the patient participating in this study is relatively low. Due to the inclusion and exclusion criteria used in this study, the 30% increase in administered iodine is unlikely to cause any renal damage.
In figure 2 of reference article 7 of the study protocol, it is shown that, for nondiabetic patients with a normal basal creatinine clearance, the expected creatinine change due to the extra contrast administration, is negligible. So, in the study population, no harm due to the extra administration of contrast agent is expected. Furthermore there is a relatively low risk for side effects and other issues for patients participating in this study.

Additional radiation dose
Derived from the clinical procedure, the value of the dose area product of a cine run is approximately 0,45 Gy.cm2. The total dose for a clinical CAG procedure is approximately 21,2 Gy.cm2. The four extra research runs, of which two are performed with a doubled dose, cause an increase in dose of 3 Gy.cm2.

For calculating the effective dose, a conversion factor of 0,30 mSvGy-1cm-2 can be used 9. The increase in effective dose due to the research runs, two of which have a doubled dose, is approximately 0,91 mSv and this means a relative increase of 14,1%.

According to the international commission on radiological protection (ICRP) the additional radiation dose as a result of the research runs should be categorised as IIA.
For this category ICRP states that acquisition of knowledge, resulting in health benefit should be obtained by a study. In this study the health benefit that is aimed for, is the decrease in kidney damage due to a reduction of administered contrast agents for patients with deteriorated renal function.

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

- referred to Isala for a clinically indicated CAG procedure
- suspected coronary artery disease (CAD)
- signed informed consent

Exclusion criteria

-age < 18 years
- incapacitated adults
- pregnant patients
- bad renal function, eGFR < 50 ml/min/1,73 m2
- corpulent patients, BMI > 30
- patients with diabetes mellitus
- patients with known contrast agent intolerance
- patients who underwent coronary artery bypass grafting
- patients with cardiogenic shock
- patients with heart failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2021
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	12-08-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-09-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-02-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-03-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64175.075.20