Myocardial mass determination of the different coronary territories by FFRct and invasive measurement of absolute coronary blood flow. A clinical Registry.

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- To compare relative myocardial mass distribution (i.e. mass of the respective territories of LAD, LCX and RCA) by CT scanning to normalized hyperemic blood flow in the three major myocardial territories as assessed by absolute flow measurements...

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

Summary

ID

NL-OMON44459

Source
ToetsingOnline

Brief title
MyoMass study

Condition

- Coronary artery disorders

Synonym
coronary disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: educational grant from Heartflow Inc.,Heartflow Inc. Redwood City. CA. USA.

Intervention

Keyword: absolute flow, FFRct (CT derived FFR), fractional flow reserve (FFR), myocardial mass

Outcome measures

Primary outcome

Het is rondom coronaire interventies zoals PCI of CABG van klinisch belang om het risico voor de patient in te schatten. Er is tot op heden geen non-invasieve methode beschikbaar om het gebied van necrose in te schatten na een myocardinfarct of procedure. Vooral bij een percutane coronaire interventie (PCI) zou het erg waardevol zijn om informatie te hebben omtrend de absolute en relatieve myocardiale massa distaal van het 'interventie gebied'. Deze informatie kan helpen bij de risico inschatting en tevens bij het bepalen van de beste revascularisatie methode bij meervatslijden. Het primaire onderzoeksdoel is dan ook het quantificeren van de hartmassa en bloedflow per coronairgebied.

Secondary outcome

not applicable

Study description

Background summary

Although knowledge about the myocardial mass (in grams) of the different territories belonging to the major coronary arteries, is of clinical importance to estimate risk of coronary interventions (PCI, CABG) and to determine area of necrosis after myocardial infarction, no invasive methodology has been

available so far for reliable assessment of mass. Especially in the setting of percutaneous coronary intervention (PCI), it would be valuable to have information about the absolute and relative myocardial mass distal to the location where the intervention is planned. Such information is valuable for risk estimation and can also be helpful in multivessel disease to determine the most adequate way of revascularization. Both MRI and CT scanning have claimed to be able to estimate myocardial mass non-invasively, but by the lack of any gold standard, none of these methods could be validated in vivo so far. A relatively new development in CT technology is the calculation of fractional flow reserve (FFR) by CT scanning, according to a sophisticated algorithm developed by Heartflow Inc. One of the baseline assumptions in that algorithm is that myocardial mass is proportional to resting blood flow, which seems a plausible assumption from a rational physiological point of view. More recently, invasive calculation of absolute blood flow has become possible as well as resistance measurement of the (microcirculation of the) myocardium. Using that invasive technology (explained in the appendix to this protocol), it can be assumed that measuring absolute maximum blood flow in a coronary artery as well as fractional flow reserve for different territories or for different spots within one major coronary artery, provides a basis for relative mass calculation. The background for performing the present study is to compare these mass calculations by CT scanning and by invasive measurements, thereby corroborating both methods.

Study objective

- To compare relative myocardial mass distribution (i.e. mass of the respective territories of LAD, LCX and RCA) by CT scanning to normalized hyperemic blood flow in the three major myocardial territories as assessed by absolute flow measurements and FFR in patients with an indication for multivessel FFR measurement.

- To compare relative myocardial mass belonging to a proximal or a mid segment of one of the major coronary arteries measured by CT scanning to invasive absolute flow and FFR measurement in that particular proximal or mid coronary artery in patients undergoing single or multivessel PCI.

Study design

Because from a scientific point of view, no reason is present to set-up this mechanistic study as a merely prospective study, also the *retrospective arm* is included. This saves money, time, and unnecessary exams in prospective patients.
Consequently, connected with this study protocol there is a regular informed consent form (for the *prospective* patients) as well as a *simple* informed consent form for anonymous use of data only (for the retrospective patients).

Study burden and risks

As the invasive procedure is not fundamentally different from a routine procedure with FFR/physiologic measurements, and the procedure is prolonged by 20-30 minutes at the average only, the risk of the procedure compared to a regular procedure is neglectable.
There is no direct benefit for the patient but the absolute flow measurements provide an index of the microcirculation of the heart which might contribute to a better understanding of his/her disease.
As for the coronary CT, the radiation exposure is equivalent to 3 mSv. For comparison, radiation exposure due to the invasive procedure is generally in the range between 10-15 mSv. For reasons of radiation safety, preferably patients will be included in whom a coronary CT scan has already been made or is indicated for clinical reasons, as is increasingly common in these patients.
In patients in whom no coronary CT is available, permission will be asked to perform such CT scan as yet. Except for contrast allergy and decreased kidney function, both exclusion criteria for this study, no direct risks are associated with the CT scan performance.

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

1) Presence of multivessel coronary disease with an indication for multivessel FFR and/or PCI or Patients with single vessel disease scheduled for FFR/PCI of that single coronary artery
2) Availability of a coronary CT scan performed prior to the scheduled invasive investigation. The time difference between the CT scan and the invasive exam should be less than 3 months.
3) Focal lesions only
4) Normal left ventricular function
5) Age < 75 years

Exclusion criteria

1) Inability to give informed consent
2) Diffuse coronary disease
3) Tortuous or calcified arteries interfering with reliable invasive FFR assessment
4) Previous myocardial infarction or ejection fraction less than 60% by echocardiography or ventriculography or less than 50% by nuclear methods
5) Atrial fibrillation interfering with high quality coronary CT scanning
6) Age > 75 years
7) Other contra-indications for CT scanning
8) Pregnancy or admired pregnancy in the future
9) Left main stenosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	16-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL62884.100.17