High-frame-rate contrast-enhanced echocardiography for left-ventricular perfusion analysis after PCI (QUANTO)

Published: 21-04-2022
Last updated: 27-04-2024

The objective of this study is three-fold: 1) Assess measurement settings and develop the data processing chain to detect contrast signals in the left-ventricular wall with contrast-enhanced high-frame rate echocardiography. Determine whether this...

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

Summary

ID

NL-OMON52121

Source
ToetsingOnline

Brief title
High-frame-rate contrast echocardiography

Condition

- Coronary artery disorders

Synonym
cardiac perfusion, heart attack, systolic dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: contrast agent, echocardiography, high frame rate imaging, perfusion

Outcome measures

Primary outcome

The primary parameter of this study is the myocardial perfusion deficit between cardiac segments and/or between the epicardial and the endocardial border, directly after percutaneous coronary intervention, as determined with high-frame rate contrast echocardiography. We expect, based on many studies of post-PCI measurements (e.g., scar tissue on MRI scans; post-mortem histology; preclinical animal testing) that there is local variation in perfusion both between segments, as well as trans-mural.

Secondary outcome

• Establish expectation of feasibility in clinical practice in / nearby the Cath lab, and in the outpatient clinic.

• Develop a comparative framework with current standard protocols for perfusion imaging (TIMI score, conventional contrast-enhanced echography)

• To explore the added value of high frame-rate echocardiography in patients that have underwent a PCI.

• Assess the blood flow in the left-ventricular cavity nearby the wall

Study description

Background summary

Yearly in the EU, about 3 million patients with a myocardial infarction (MI; i.e. *heart attack*) receive a minimally-invasive intervention (opening the

obstructed coronary artery with a balloon on a catheter and usually placing a stent) followed by pharmaceutical treatment. Even after successful re-canalisation of coronary arteries by catheter interventions (percutaneous coronary intervention, PCI) in the Cath Lab, a substantial (~30%) part of hearts still show local perfusion deficits in the culprit region. The exact origin is unknown and may be diverse, hence follow-up treatment is not successful. We aim to develop new ultrasound contrast-enhanced perfusion imaging systems to show perfusion deficits in real time in the Cath Lab, such that candidate follow-up treatments can be tested immediately after re-canalisation. This current protocol presents the first three stages of testing the imaging system in patients, yet (just) outside of the Cath Lab.

Study objective

The objective of this study is three-fold:

1) Assess measurement settings and develop the data processing chain to detect contrast signals in the left-ventricular wall with contrast-enhanced high-frame rate echocardiography. Determine whether this potentially shows perfusions deficits between cardiac segments, and whether perfusion differences are visible in a 3-6 month PCI follow-up.

2) Establish the feasibility of measuring myocardial perfusion with high-frame rate echocardiography in patients that have underwent a PCI or are hospitalized for cardiac disease.

3) Assess the blood flow in the left-ventricular cavity near the wall.

Study design

This will be an observational cohort study divided into four stages. The first two stages are intended for fine-tuning the acquisition and post-processing techniques, while the third and fourth stage will investigate actual discriminative power for cardiac perfusion deficiency imaging. The study will take place within the Cardiology department of Erasmus MC. Patients will be examined first with conventional non-contrast AND contrast-enhanced echography, following their respective regular clinical diagnostic protocols to provide the diagnostic value for the treating physician. For these contrast-enhanced echography exams, they will receive a canula (intravenous line) in their forearm to administer the ultrasound contrast agent. That clinical exam also provides part of the reference data for the high frame rate technique. Subsequently, we will use our high frame rate imaging protocol and equipment to capture the data, analyse the data, and compare the outcome to the reference data (symptoms, echocardiography, contrast-CT if available from routine care, intervention data, disease history).

Study burden and risks

The burden of the study procedures consists of extension of the echocardiographic study which the patient undergoes during the regular visit to the echocardiography clinic at Erasmus MC (stage 1 and 4B), performing an echocardiographic exam in the hospital during admission (stage 2), during open heart surgery (stage 3) or on the medium care unit after percutaneous coronary intervention in the Cath Lab (stage 4A). Patients will be invited to participate and with permission of the patient clinical data from the clinical interview and physical examination may be retrieved from the medical files. The study is an observational study, physical and physiological discomfort for the patients is very limited. The ultrasound contrast agent is safe and registered for the use during echocardiography. There is a small risk of an allergic reaction after administration of ultrasound contrast agent (0.01%). During all examinations a medical doctor will be present to react immediately in case of an allergic reaction. Additional blood tests will not be required. The risks associated with participation can be considered negligible and the burden can be considered minimal.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Aged >= 18 years.
• Capable of understanding and signing informed consent.
• Stage 1:
o scheduled for conventional contrast-enhanced echocardiography
• Stage 2:
o Admitted to the Erasmus MC Cardiology ward for an elective cardiac procedure
• Stage 3:
o Admitted to the Erasmus MC Cardiology ward
o Planned for cardiac surgery
• Stage 4A:
o underwent PCI in the past hour;
o is recovering in the medium-care unit;
o is physiologically stable and awake;
o suffered a single-vessel ST-elevated myocardial infarction
o still carries an intravenous line;
o oral explicit approval by the treating intervention cardiologist to perform a contrast-enhanced echographic study in the medium-care unit for this patient.
• Stage 4B:
o Was included in stage 4A, at most 6 months before (range: 3 - 6 months)
o Is physiologically stable
o Has had no serious adverse events or other cardiac complaints/STEMIs in the mean time

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Patients living abroad or who are not Dutch speaking;
• Any contra-indication for contrast media Sonovue (Bracco International bv, Amsterdam), or Luminity (Dutch supplier: LamePro bv, Breda);
• Patients with inability to obtain adequate echocardiographic examination;
• Pregnant and/or lactating women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-02-2023
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	Echographic scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-04-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-04-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL77620.078.22