Artifact free carotid contrast-enhanced ultrasound

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Repeating the phantom study in human subjects will provide us the answer which of the new pulse-sequences should be used for future contrast-enhanced ultrasound studies.

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON38664

Source
ToetsingOnline

Brief title
Artifact free carotid contrast-enhanced ultrasound

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arterial calcification, atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: contrast-agent, Non-invavsive, ultrasound, vascular

Outcome measures

Primary outcome

Lumen intensity

Artifact intensity

Secondary outcome

Differences in amount of intra-plaque neovascularization will be detected using automated quantification software developed for the evaluation of intra-plaque neovascularization.

Study description

Background summary

In the Erasmus Medical Center, multiple studies investigated the clinical value of vascular contrast-enhanced ultrasound. One of the conclusions of a prior study was that the ultrasound clips are hindered by an artifact, resulting in ultrasound clips that are not suitable for analysis. This artifact is caused by the way the ultrasound pulse-sequences behave in the human body. By adjusting these sequences, a solution for this artifact could be provided. To prove that the new pulse-sequences perform better than the current pulse-sequences, we have to perform a observational comparison study. Such a study is allready performed in a phantom. However, that controlled setting does not provide a realistic view of the human neck.

Study objective

Repeating the phantom study in human subjects will provide us the answer which of the new pulse-sequences should be used for future contrast-enhanced ultrasound studies.

Study design

Observational study.

Study burden and risks

Ultrasound contrast agent will be administered intravenously. This ultrasound contrast agent is safe (see references) and is registered for contrast-enhanced echocardiography. The chance of een allergic reaction after administration of ultrasound contrast agents is limited. During each examination, a medical docter will be present. In case of allergic reactions he will intervein immediately.

Main ML, Ryan AC, Davis TE, Albano MP, Kusnetzky LL, Hibberd M. Acute mortality in hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent (multicenter registry results in 4,300,966 consecutive patients). Am J Cardiol 2008;102:1742-6.

Kusnetzky LL, Khalid A, Khumri TM, Moe TG, Jones PG, Main ML. Acute mortality in hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent: results in 18,671 consecutive studies. J Am Coll Cardiol 2008;51:1704-6.

Wei K, Mulvagh SL, Carson L, Davidoff R, Gabriel R, Grimm RA, e.a. The safety of deFinity and Optison for ultrasound image enhancement: a retrospective analysis of 78,383 administered contrast doses. J Am Soc Echocardiogr 2008;21:1202-6.

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. Prior participation in the VASA study (ABR-number: 28698)
2. Age over 18 years

Exclusion criteria

1. Unstable clinical symptoms
2. Contraindications for contrast-enhanced ultrasound

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):	01-01-2013
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2013
Application type:	First submission
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	NL42873.078.12