Feasibility study of a non-contrast MRI-scan for breast cancer screening using Velocity Selective Arterial Spin Labeling

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Primary Objective: To study the feasibility of Velocity Selective Arterial Spin Labeling as a non-invasive technique for breast cancer screening by comparing image quality with DCE-MRI.Secondary Objectives: Comparing tumor characteristics and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON50007

Source
ToetsingOnline

Brief title
Non-contrast MRI breast cancer screening

Condition

- Miscellaneous and site unspecified neoplasms benign
- Breast disorders

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: ASL, Breast cancer, MRI

Outcome measures

Primary outcome

As the main study parameter VS-ASL and DCE-MRI scans will be compared on image quality based on visual scoring of three experienced radiologists. The readers will be blinded to original study interpretations.

Secondary outcome

As secondary study parameter VS-ASL and DCE-MRI scans will be compared based on quantitative lesion characteristics, e.g. tumor size, relative signal enhancement of tumor, etc, as well as overall suspicion for cancer.
In addition, VS-ASL and DCE-MRI outcome will be compared to biopsy results (if available).

Study description

Background summary

In breast cancer, patients benefit greatly from early stage detection; 5-year survival rate is 90% for patients with early-stage detection and 15% for women with detection at most advanced stage of disease. Dynamic contrast enhanced (DCE) MRI has proven to increase sensitivity for breast cancer detection compared to mammography alone, and is currently the standard method for screening of women with an increased risk of developing breast cancer, e.g. women with a BRCA-gene mutation. DCE-MRI scans rely on intravenous administration of gadolinium (Gd)-contrast, which is associated with gadolinium retention and nephrogenic systemic fibrosis. However, in breast cancer screening, healthy women with a high risk of developing breast cancer will undergo Gd-DCE MRI scans annually from the age of thirty. Since doubts have been raised about the side-effects of Gd-containing contrast agents it becomes desirable to have an alternative to the administration of contrast agent.
Velocity Selective Arterial Spin Labeling (VS-ASL) is an MR-perfusion technique

that does not require administration of contrast agent. While other ASL methods have problems obtaining enough signal in breast because of the complicated vascular bed and slow flow, VS-ASL is more suitable, because it creates signal closer to the target tissue. Feasibility and optimization of VS-ASL as breast cancer screening-tool will need to be performed in patients with (early-stage) breast cancer, since contrast in perfusion images will be too low to validate and optimize this technique in healthy volunteers.

Study objective

Primary Objective:
To study the feasibility of Velocity Selective Arterial Spin Labeling as a non-invasive technique for breast cancer screening by comparing image quality with DCE-MRI.

Secondary Objectives:
Comparing tumor characteristics and overall suspicion of cancer of VS-ASL and DCE-MRI scans.
Comparing VS-ASL and DCE-MRI outcome to biopsy results (if available).

Other Objective:
To further optimize the VS-ASL technique by varying sequence parameters.

Study design

Single-center feasibility study

Intervention

All patients participating in the study will undergo a single additional non-invasive MRI scan.

Study burden and risks

There are no known risks or adverse effects to MRI, beside occasional dizziness and claustrophobia. VS-ASL is a standard MRI-scan technique, not needing any contrast agent, and not posing any additional burden or risk to the patient. Therefore, burden for subjects can be considered to be relatively low in this study. Since the patients would undergo the MRI examination including DCE-MRI irrespective of their participation in the study, it is not expected that the additional VS-ASL scan will provide new diagnostic information and this scan will not be used for clinical purposes.
The only concern is that the VS-ASL scan needs to be acquired prior to contrast agent injection, whereas the contrast-enhanced scans are needed for clinical purposes. To avoid the possibility that after the VSASL-scan the patient is not able to finish the examination, we will ask the subject prior to the VSASL scan

whether she is willing to undergo the additional 7 min of scanning.

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

female patients scheduled for an MR-breast scan
patients volunteer to participate and are capable and prepared to sign an informed consent
patients of 18 years or older.

Exclusion criteria

patients who would otherwise not an undergo MR-breast scan
patients who are not able or willing to comply with breathing instructions
patients with contra-indications for Gadolinium-contrast agents
patients who underwent breast reduction.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL70510.058.19