Contrast kinetics in dynamic contrast-enhanced MRI of the breast in patients with histologically proven breast cancers with and without a computer aided detection system.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	-

Summary

ID

NL-OMON22751

Source
Nationaal Trial Register

Health condition

MRI, CAD, Computer Aided Detection system, breast, Gadobutrol

Sponsors and support

Primary sponsor: Atrium Medisch Centrum Parkstad
Source(s) of monetary or material Support: Atrium Medisch Centrum Parkstad. Investigator initiated studied with financial support from Bayer Healthcare

Intervention

Outcome measures

Primary outcome

The initial rate of enhancement, the maximum enhancement, and the percentage decrease

in enhancement in the signal intensity-time curves measured at the last time point relative to the maximum enhancement within the first 120 seconds post contrast agent administration will be determined with and without the use of the CAD-system.

Secondary outcome

Interobserver variability with and without the use of the CAD-system will be determined

Study description

Background summary

Rationale
When performing a MRI scan of a breast lesion, dynamic contrast-enhanced series are important for lesion characterization by providing information about the rate and shape of enhancement of the lesion over time. These signal intensity-time curves can add value in differentiating malignant from benign lesions. Signal intensity-time curves are commonly presented as a single curve for a specific region of interest. Another method is to analyse and quantify the contrast enhancement in every pixel over time and present the results as a colour-coded map.

The goal of this exploratory study is to directly compare quantitative enhancement parameters (the contrast agent kinetics) between 1.0 molar Gadobutrol with and without the utilisation of a Computer Aided Detection system (CAD) in patients with histologically proven breast cancers initially classified as BIRADS 5, undergoing dynamic contrast-enhanced MRI of the breasts.

Study objective

The goal of this exploratory study is to directly compare quantitative enhancement parameters (the contrast agent kinetics) between 1.0 molar Gadobutrol with and without the utilisation of a Computer Aided Detection system (CAD) in patients with histologically proven breast cancers initially classified as BIRADS 5, undergoing dynamic contrast-enhanced MRI of the breasts.

Study design

Dynamic contrast-enhanced MRI of the breasts will be reported in daily practice by breast radiologists. Data collection for this study will be performed in separate sessions for the manual collected enhancement characteristics and the CAD assisted enhancement characteristics. The researchers will be blinded to the patient data. Statistical analysis will be performed after all patients have been included.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

•At least 18 years of age
•Histologically proven breast cancer (BIRADS 5)
•Patients who are willing to undergo study procedures

Exclusion criteria

•Patients who have previously entered this study
•Patients who are or are suspected in pragnancy or nursery
•Patients with a contraindication for MRI
•Patients who have received any contrast material within 48 hours prior to injection with study or comparator drug.
•Patients who require emergency treatment
•Patients with impaired renal function of CKD stadium 3 and higher (e.g. creatinine clearance < 60ml/ min). In patients with known renal impairment, clearance will be calculated based on serum creatinine level using the Cockroft-Gault formula. Calculation of the clearance must be done before begin of study.

•Patients with known anaphylactoid or anaphylactic reaction to any contrast media

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2015
Enrollment:	30
Type:	Unknown

Ethics review

Positive opinion

Date:	30-12-2014
Application type:	First submission

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
NTR-new	NL4833
NTR-old	NTR4956
Other	: 14-N-118

Study results