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.

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON22751

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Atrium Medisch Centrum Parkstad
Overige ondersteuning: Atrium Medisch Centrum Parkstad.
Investigator initiated studied with financial support from Bayer Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•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

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	30
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	30-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4833
NTR-old	NTR4956
Ander register	: 14-N-118

Resultaten