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Can an MRI scan show early signs of medication-related changes to the heart in patients with breast cancer treated with trastuzumab?

Submission date
14/11/2018

Recruitment status
No longer recruiting

Registration date
23/11/2018

Overall study status
Completed

Last Edited
23/11/2018

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Trastuzumab is a drug that targets oestrogen signalling and can be used to treat selected breast cancer patients. It has been shown to delay and prevent death from breast cancer. However, with more patients surviving breast cancer, it becomes more important to prevent side effects. Trastuzumab can lead to heart failure in up to a quarter of patients receiving this drug. In most cases this heart failure is reversible after trastuzumab treatment finishes. However, these patients have higher lifetime risk of heart problems such as chronic (long-lasting) heart failure, myocardial infarctions (heart attacks) or other forms of heart disease. Until now, the main way to prevent trastuzumab-associated heart failure is repeated screening using echocardiography (ultrasound scanning of the heart). It is possible that MRI scans of the heart might show the early signs of heart failure resulting from trastuzumab treatment long before symptoms occur. This study aims to compare heart MRI scans before, during and after trastuzumab therapy and to identify the MRI changes that best predict which patients will later develop trastuzumab-associated heart failure. Doing this we might be able to make trastuzumab therapy safer in the future.

Who can participate?
Adult patients with breast cancer who are expected to be treated with trastuzumab

What does the study involve?
All participants receive heart MRI scans before, during and after five treatments with trastuzumab. All participants receive treatment for their breast cancer as usual.

What are the possible benefits and risks of participating?
Participants might benefit from earlier detection of heart problems using MRI compared to ultrasound. During the MRI scan, participants receive a standard dose of contrast medium that in rare occasions can cause allergic reactions. However, there are no study-associated side effects that exceed those of a regular MRI scan.

Where is the study run from?
HELIOS Hospital Berlin-Buch (Germany)

When is the study starting and how long is it expected to run for?
June 2018 to December 2020

Who is funding the study?
The cost of this study will be funded by the research group itself through university-affiliated research grants. No external funding is needed.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HER2-CMR

Study information

Scientific Title
Prediction of trastuzumab-associated cardiomyopathy using cardiovascular MRI

Acronym
HER2-CMR

Study objectives
Trastuzumab is known to be induced reversible and irreversibly congestive heart failure. We hypothesized that cardiac MRI is able to detect early changes in the myocardial structure after the first application of trastuzumab but long before clinical signs of heart failure occur. In detail, we hypothesized that myocardial T1 times change very early after start of trastuzumab.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charité University Medicine Berlin Ethics Board (Campus Mitte), 23/10/2018, ref: EA1/176/18

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Trastuzumab-associated cardiomyopathy

Interventions
Participants receive a maximum of four cardiac MRIs. One MRI before start of chemotherapy (which typically happens before start of trastuzumab), one MRI directly before start of trastuzumab, one MRI directly before the second administration of trastuzumab and one MRI after 5 cycles of trastuzumab.

Intervention Type
Device

Primary outcome(s)
Mean native myocardial T1 time measured using MRI (MOLLI sequences) at all time points (before start of chemotherapy, before the first dose of trastuzumab, before the second dose of trastuzumab and after 5 cycles of trastuzumab)

Key secondary outcome(s))
1. Left ventricular ejection fraction
2. Myocardial T2 time
3. Late gadolinium enhancement
4. Longitudinal strain
5. Circumferential strain
All secondary outcome measures are assessed using MRI at all time points (before start of chemotherapy, before the first dose of trastuzumab, before the second dose of trastuzumab and after 5 cycles of trastuzumab).

Completion date
31/12/2020

Eligibility

Key inclusion criteria

1. Mammary carcinoma
2. Planned trastuzumab therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any absolute contraindication for MRI
2. Chronic renal failure with GFR <30 ml/min/m2 at time of inclusion

Date of first enrolment
30/11/2018

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
Germany

Study participating centre
HELIOS Hospital Berlin-Buch
Schwanebecker Chaussee 50
Berlin
Germany
13125

Sponsor information

Organisation
Working Group Cardiac MRI @ Charité University Medicine Berlin & HELIOS Hospital Berlin-Buch

ROR
https://ror.org/05hgh1g19

Funder(s)

Funder type
University/education

Funder Name
Working Group Cardiac MRI @ Charité University Medicine Berlin & HELIOS Hospital Berlin-Buch

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to reasons of data protection laws in Germany. However, upon request methodology and data set structure can be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes