

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

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<b>Registration date</b> 23/11/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/11/2018	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?  
Dr Fabian Muehlberg  
Fabian.muehlberg@helios-gesundheit.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Fabian Muehlberg

**ORCID ID**  
<https://orcid.org/0000-0002-7981-5178>

**Contact details**  
HELIOS Hospital Berlin-Buch/Working group Cardiac MRI  
Schwanebecker Chaussee 50  
Berlin  
Germany  
13125

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

**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 measure**

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)

**Secondary outcome measures**

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).

**Overall study start date**

01/06/2018

**Completion date**

31/12/2020

## Eligibility

**Key inclusion criteria**

1. Mammary carcinoma
2. Planned trastuzumab therapy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Any absolute contraindication for MRI
2. Chronic renal failure with GFR <30 ml/min/m<sup>2</sup> 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

### Sponsor details

Lindenberger Weg 80  
Berlin  
Germany  
13125

### Sponsor type

University/education

### 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

### Publication and dissemination plan

We are intending to publish at least one research article in a high-ranking peer-reviewed journal, such as JCMR (impact factor 6.5)

### Intention to publish date

31/12/2020

### 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