

# Magnetic resonance imaging vs invasive coronary angiography as first-line diagnostic modality in new-onset heart failure

<b>Submission date</b> 21/08/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/08/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/07/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Newly diagnosed heart failure requires a comprehensive diagnostic work-up to determine its underlying cause. This work-up frequently includes a procedure called invasive coronary angiography (CATH). There are also alternatives, such as a non-invasive procedure called cardiac magnetic resonance imaging (CMR). The aim of this study is to find out whether CMR can diagnose the underlying cause of heart failure as well as CATH. If so, this would reduce the number of invasive procedures.

### Who can participate?

Patients aged 18 years and over with newly diagnosed heart failure and a reduced left ventricular ejection fraction (i.e., below or equal to 40%, measured by echocardiography).

### What does the study involve?

The study takes part in a routine clinical setting. All participants receive both diagnostic tests but the order is randomly allocated.

### What are the possible benefits and risks of participating?

CATH is currently the standard procedure for newly diagnosed heart failure, so there is no added risk. CMR is a widely available diagnostic test which is non-invasive and involves the use of contrast media (as does CATH). Kidney function is closely observed during the study. The potential benefit is receiving an excellent diagnostic test (CMR), which in many instances can yield additional information that cannot be obtained by CATH.

### Where is the study run from?

University Hospital Würzburg (Germany)

### When is the study starting and how long is it expected to run for?

May 2015 to January 2024

Who is funding the study?  
German Cardiac Society

Who is the main contact?  
Prof. Dr. med. Stefan Störk, PhD, stoerk\_s@ukw.de

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Stefan Störk

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Diagnostik Study

## Study information

### Scientific Title

Diagnostic value of cardiac magnetic resonance imaging vs coronary angiography as primary diagnostic strategy in heart failure with reduced ejection fraction – the randomized CMR-first /CATH-first study

### Acronym

DIAGNOSTIK STUDIE

### Study objectives

Obtaining sufficient diagnostic information already from the first diagnostic procedure to satisfactorily establish or exclude ischemic origin of heart failure: "yes or no", rendering the second diagnostic procedure redundant

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 19/04/2018, Ethik-Kommission der Universität Würzburg (Versbacher Str. 9, Würzburg, 97078, Germany; +49 (0)931 31 48315; ethikkommission@uni-wuerzburg.de), ref: 298/17

### **Study design**

Randomized diagnostic controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Newly diagnosed heart failure

### **Interventions**

Participants are centrally randomised 1:1 to either coronary angiography first (CATH) followed by cardiac resonance imaging (CMR), or CMR first followed by CATH. Randomisation is done electronically in blocks, stratified based on left ventricular ejection fraction (LVEF)  $\leq 25\%$  vs  $>25\%$  according to the study-qualifying echocardiography.

For endpoint evaluation, the results of each examination are presented separately to a CMR and a CATH expert panel, each blinded to the other procedure. The panel evaluates whether the cause of HF was ischemic and assesses the necessity to perform the other modality.

Additionally, all examinations of both strategies (CATH-first and CMR-first) are also evaluated by the consulting cardiologist, who has access to all available data (clinical reference standard) and is blinded to the evaluation of the expert panels.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Ischaemic cause of heart failure diagnosed via CMR or CATH procedure used as the first modality at baseline

### **Key secondary outcome(s)**

Number of CATH procedures that could be avoided when applying the CMR-first strategy: this metric is operationalized as the number of patients in whom the CMR done as a first diagnostic test allowed the researchers to omit an invasive CATH procedure (measured at baseline)

### **Completion date**

31/01/2024

## Eligibility

### Key inclusion criteria

1. Age  $\geq 18$  years
2. Physical and mental ability to give informed consent
3. Written informed consent for study participation
4. Indication for coronary angiography and signed copies of patient information forms for coronary angiography and CMR
5. Heart failure with reduced ejection fraction and a left ventricular ejection fraction  $\leq 40\%$  in echocardiography (or comparable imaging modality) within the preceding 3 months
6. Cause of heart failure not yet determined
7. Hospital admission for coronary angiography for further evaluation of heart failure origin or in case of primary in-hospital diagnosis of HFrEF, clinical indication for coronary angiography after best possible cardiac recompensation

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

229

### Key exclusion criteria

1. Pregnancy
2. End-stage renal disease (glomerular filtration rate  $< 30$  ml/min/m<sup>2</sup> (MDRD) and/or dialysis-dependency)
3. Acute coronary syndrome
4. History of coronary artery disease or myocardial infarction
5. Acutely decompensated heart failure or heart failure stage NYHA IV
6. Valvular stenosis (any)  $\geq$  grade II
7. Standard exclusion criteria for cardiac MRI (e.g., incompatible metallic implants or devices, known claustrophobia, allergy against gadolinium-based contrast agents, bodily dimensions incompatible with scanner)

### Date of first enrolment

22/11/2018

**Date of final enrolment**

31/01/2024

**Locations****Countries of recruitment**

Germany

**Study participating centre****University Hospital Würzburg**

Oberdürrbacher Straße 6

Würzburg

Germany

97070

**Study participating centre****University of Leipzig**

Liebigstraße 20

Leipzig

Germany

04103

**Study participating centre****Medizinische Hochschule Hannover**

Carl-Neuberg-Straße 1

Hannover

Germany

30625

**Study participating centre****Klinikum Nürnberg**

Breslauer Str. 201

Nürnberg

Germany

90471

**Sponsor information****Organisation**

German Cardiac Society

ROR

<https://ror.org/02p22ad51>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Investigator-initiated diagnostic trial

### Funder Name

Deutsche Gesellschaft für Kardiologie-Herz und Kreislaufforschung.

### Alternative Name(s)

German Cardiac Society, Deutsche Gesellschaft für Kardiologie, Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V., DGK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Associations and societies (private and public)

### Location

Germany

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study can be made available upon request from Stefan Störk ([stoerk\\_s@ukw.de](mailto:stoerk_s@ukw.de)).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/07/2025	14/07/2025	Yes	No
<a href="#">Participant information sheet</a>	version 1.3	30/08/2019	22/08/2024	No	Yes

[Protocol file](#)

version 1.6 14/01/2021 22/08/2024 No

No