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

Submission date
21/08/2024

Recruitment status
No longer recruiting

Registration date
22/08/2024

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

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) </=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 measure

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

Secondary outcome measures
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)

Overall study start date
12/05/2015

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Age ≥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 ≤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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
229

Key exclusion criteria
1. Pregnancy
2. End-stage renal disease (glomerular filtration rate <30 ml/min/m² (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) ≥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

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Sponsor type
Other

Website
https://dgk.org/

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

Publication and dissemination plan
Results will be published at the Late Breaking Trial Session at the ESC London, September 2024.

Intention to publish date
01/10/2024

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).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	30/08/2019	22/08/2024	No	Yes
Protocol file	version 1.6	14/01/2021	22/08/2024	No	No
Results article		12/07/2025	14/07/2025	Yes	No