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Risk assessment for chronic coronary heart disease by general practitioners: Using the Cardio Explorer in primary care

Submission date 26/08/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/09/2024	**Overall study status** Ongoing	
Last Edited 04/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Coronary heart disease is still considered a widespread disease in Germany despite slightly declining mortality rates. The challenges in the early detection of patients with coronary heart disease in combination with developments in healthcare policy (e.g. limited specialist resources combined with long waiting times) show the considerable need to improve risk assessment in primary care. This study investigates the implementation of an artificial intelligence-based algorithm, the Cardio Explorer. The main goal is to investigate the level of acceptance, usability and trust in the Cardio Explorer by general practitioners.

Who can participate?
People (≥ 50 years of age) who are suspected of having coronary heart disease when they present to their general practitioner. Participants must be insured with AOK Niedersachsen.

What does the study involve?
Participants will be allocated to the control group versus the treatment group based on the time of presenting to the general practitioners (control phase or intervention phase). General participants apply the Cardio Explorer to assess the clinical likelihood of coronary heart disease. Each participant is documented after medical consultation and participants are monitored before and after using claims data from the AOK Niedersachsen.

What are the potential benefits and risks of participating in the study?
General practitioners have access to the Cardio Explorer, which is a non-invasive innovative tool. Participation might reduce unnecessary (invasive) diagnostic procedures that are associated with risks (e.g. vascular injuries and bleeding, embolism and strokes, kidney failure, cardiac arrhythmias). Other causes of the presented symptoms could be recognized more quickly and thus treated more efficiently. The input data for the Cardio Explorer is determined as part of routine blood analysis and assessment of the medical history. Accordingly, additional medical procedures are not needed to apply the Cardio Explorer. General practitioners are free to use additional tools to assess the individual risk of coronary heart disease.

Where is the study run from?
General practitioner practices in Lower Saxony in Germany.

When is the study starting and how long is it expected to run for?
Preparations for the study began in February 2023. Data assessment (control phase followed by the intervention phase) takes place from November 2024 to December 2025. The study is expected to end in July 2026 with the submission of a final report.

Who is funding the study?
The insurance company AOK Niedersachsen
Exploris Health AG provides pseudo-anonymised input data from Cardio Explorer

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pilot study on using the Cardio Explorer for coronary heart disease risk assessment in primary care

Study objectives
1. Primary hypothesis: the results of the risk assessment provided by the Cardio Explorer and the medical (diagnostic) procedure of the general practitioner match by at least 90%
2. Secondary hypothesis: The benefit of using the Cardio Explorer in primary care rated by general practitioners is high.
3. Secondary hypothesis: Confidence in the Cardio Explorer rated by general practitioners is high.
4. Secondary hypothesis: The level of usability and practicability of the Cardio Explorer in primary care rated by general practitioners is good.
5. Secondary hypothesis: The use of the Cardio Explorer decreases (invasive) diagnostic procedures.
6. Secondary hypothesis: The use of the Cardio Explorer decreases contacts with cardiologists.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/09/2023, Ethics Committee of the Medical Association of Lower Saxony (Ethikkommission bei der Ärztekammer Niedersachsen) (Berliner Allee 20, Hannover, 30175, Germany; +49 511 3802-3102; ethikkommission@aekn.de), ref: BO/28/2023

Study design
Multicentred controlled non-randomized study with prospective observation of the intervention and control group (quasi-experimental study design)

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Coronary heart disease

Interventions
This is a multicentre, controlled, non-randomized study with prospective observation of both the intervention and control groups (quasi-experimental study design).

Patients included in the study during the control phase will be assigned to the control group and will receive standard care. In the subsequent intervention phase, general practitioners (GPs) will use the Cardio Explorer, and patients included during this period will be assigned to the treatment group.

Data assessment will be based on three sources: First, during both the control and intervention phases, GPs will complete an electronic Case Report Form to record patient information and medical procedures. GPs will also participate in qualitative interviews and standardized questionnaires to evaluate the usability of the Cardio Explorer. Secondly, claims data provided by AOK Niedersachsen on diagnostic procedures will be retrieved for up to one year before, and six months after, the control and treatment phases respectively. Thirdly, input data from the Cardio Explorer will be assessed, but only in the treatment group.

During the intervention phase, GPs will use the Cardio Explorer during medical consultations with patients suspected of having coronary artery disease (CAD).

The Cardio Explorer is a software-based medical device approved for the European market (following Directive 98/79/EC) that estimates the clinical likelihood of CAD. The input data for the Cardio Explorer consists of medical history, vital data, and laboratory values derived from a routine blood test. GPs will determine the corresponding input data as part of a standardized anamnestic examination and routine blood analysis.

The Cardio Explorer will generate a quantitative risk score with corresponding risk classification: based on the individual risk score, patients will be categorized into one of four risk classes, indicating the likelihood of CAD and the recommended diagnostic actions. The Cardio Explorer can be accessed from a local computer using any Internet browser.

Intervention Type
Other

Primary outcome(s)
Concordance between the recommended medical actions based on the Cardio Explorer risk class and the medical (diagnostic) procedure, both assessed during the intervention phase. The Cardio Explorer risk class is determined for each patient at one point throughout individual treatment (application of the Cardio Explorer). The medical (diagnostic) procedure determined by the GP is assessed at the end of treatment for each patient using a self-developed questionnaire (electronic Case Report Form).

Key secondary outcome(s))
1. The GPs’ ratings on the benefit of facilitation of risk assessment are measured using a self-developed questionnaire at the end of treatment for each patient (electronic Case Report Form). Ratings on the benefit of the risk assessment derived from qualitative interviews with GPs at the end of the intervention phase are considered as well.
2. The confidence among GPs in the risk assessment of the Cardio Explorer measured using a self-developed questionnaire at the end of treatment for each patient (electronic Case Report Form) during the intervention phase
3. GPs' good usability and practicality (usefulness, ease of use, ease of learning and satisfaction) of the Cardio Explorer measured using the standardized USE questionnaire (Usefulness, Satisfaction and Ease of use) at the end of the intervention phase. Subjective ratings (advantages and disadvantages) regarding the implementation of the Cardio Explorer derived from qualitative interviews are considered.
4. The effects on the indication for diagnostic procedures measured via the type and number of diagnostic procedures based on claims data during the follow-up period. In addition, the subjective ratings of the GPs on the reduction of unnecessary diagnostic procedures derived from qualitative interviews at the end of the intervention phase are considered.
5. The effects on the demand for treatment by cardiologists are measured by the number of

patient visits to cardiologists based on claims data (follow-up period) as well as subjective ratings among GPs derived from qualitative interviews at the end of the intervention phase.

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Insured with AOKN at the time of inscription and for the duration of study
2. Age ≥50 years
3. Suspected coronary heart disease
4. Residing in Niedersachsen or bordering area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Sex
All

Key exclusion criteria
1. Pre-existing diagnosis of coronary heart disease
2. Acute coronary syndrome / other medical emergencies
3. Participation in any clinical study (self-report)
4. Participation in the control group disqualifies from participation in the intervention group

Date of first enrolment
01/11/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Germany

Study participating centre

-
-
Germany
-

Sponsor information

Organisation
AOK

ROR
https://ror.org/004cmqw89

Funder(s)

Funder type
Industry

Funder Name
AOK Niedersachsen

Funder Name
Herz und Gefäßzentrum Bad Bevensen

Funder Name
Exploris Health AG

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 privacy and ethical concerns with respect to sensitive health data.

IPD sharing plan summary
Not expected to be made available