PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Describing, understanding and reacting upon variations in cardiac catheterization - the KARDIO study

Trial Acronym

[---]*

URL of the trial

https://www.uni-marburg.de/de/fb20/bereiche/methoden-gesundheit/allgprmed/forschung/versorgung/kardio-studie

Brief Summary in Lay Language

Chest pain is a common and serious cause for consultation. In general practices, about 10 to 15% of complaints are due to coronary heart disease (CHD). The German Clinical Practice Guidelines (CPGs) (NVL-KHK) provides a scientifically based recommendation on the practice of physicians for patients with suspected CHD and / or chest pain.
The NVL-KHK recommends that "non-invasive diagnostics" such as CT, MRI and scintigraphy be preferable to cardiac catheterization (CC). Not only does HK cause significant costs to the healthcare system, it also adds risks to patients, so needs-based care is significant.
In Germany, the number of cardiac catheters varies greatly regionally. This suggests that the implementation of the NVL-KHK is not yet widespread.
We have selected four high-coverage regions based on routine data. The physicians resident there are invited to jointly create a clinical pathway for their region (district). This clinical pathway should serve as a "tool" to adapt the recommendations of the NVL-KHK to the specific regional circumstances. Such regional features include, for example, the access / presence of non-invasive tests and arrangements of doctors (referral management). In addition, patients should be increasingly involved in decision-making and a decision aid developed by the German Agency in Quality for Medicine (ÄZQ) should support this.
The study compares the care of patients with chest pain or suspected CHD before and after development of the clinical pathway. For this purpose, GPs, cardiologists and hospitals recruited 200 patients per region at each time point. Over the phone, the patients are asked about investigations, decision-making and quality of life. In addition, we also interview the participating physicians about the implementation and clarification of the patients (symptoms, examinations, diagnosis). The survey takes place immediately after the patients have been enrolled due to complaints and three months later.

Brief Summary in Scientific Language

Background: The diagnostic process for coronary heart disease (CHD) is clearly illustrated in the German National Care Guideline Clinical Care Guidelines KHK;

plays a secondary role. Nevertheless, comparing internationally, in Germany many CC are performed with high regional variations. It is not known why there is such a high variation of CC in Germany and how these differences are due to a quality deficit in the high or low supply regions. It is obvious that the implementation of the Clinical Care Guidelines-KHK is not yet widespread.
Objective: The aim of the study is to improve the quality of care of patients with suspected CHD through the use of regionally developed clinical pathways (CP).
Setting, study participants: Within the KARDIO study, we develop, implement and evaluate regional pathways (clinical pathway) for the medical clarification of patients with a possible CHD. Our goal is to involve all regionally relevant groups of physicians (general practiotioners, cardiologists, emergency physicians, radiologists, nuclear physicians) in one region (district). The target group are patients (> 18 years) with symptoms of CHD (chest pain or equivalent). We have selected four high-supply example regions based on routine data, geographic and pragmatic (research infrastructure) as study regions.
Study design: This is a controlled before-and-after study using a complex intervention (clinical pathway). According to the recommendations of the MRC, we classify the study as Phase II-III. First, the traditional treatment in the region is recorded (control phase, "before"). After the development of CP, the intervention phase in which CP is applied, begins. In addition, we carry out a health economic analysis and a qualitative process evaluation.
Endpoints: Primary endpoint is the proportion of patients with left heart catheter to describe the change in the variation of CC. As a secondary target criterion, we assess the use of non-invasive diagnostics. The use of services is captured during the telephone interview with the help of the (modified) FIMA. Other secondary outcome criteria cover the patient perspective: shared decision-making (PEF-9); health-related quality of life (EQ-5D-5L), and CHD-specific quality of life (MacNew Heart Disease Health-related Quality of Life Questionnaire). To describe care, we also collect symptoms reported by physicians, examinations and diagnosis (own questionnaire based on the NVL-KHK and the Marburger Herz-Score). As part of the process evaluation, we conduct qualitative interviews with the participating physicians and evaluate notes on recruitment. In addition, we carry out a health economic evaluation.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021165**
- Date of Registration in DRKS: **2020/03/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **26/18 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I25 - Chronic ischaemic heart disease**
- ICD10: **I20 - Angina pectoris**
- ICD10: **R07 - Pain in throat and chest**

Interventions/Observational Groups

- Arm 1: **"Before" (control phase): conventional treatment or diagnostics**
- Arm 2: **"After" (intervention phase): treatment or diagnostics according to a regional pathway developed by peers (clinical pathway)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Health care system**
- Assignment: **Other**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Frequency of cardiac catheterization
(Telephone patient survey on use of services (modified FIMA) in intervention and control groups, each at T1 = 3 months)

Secondary Outcome

Frequency of non-invasive diagnostics to clarify CHD
Survey: Telephone patient questionnaire on the use of services (modified FIMA) in the intervention and control groups, each at T1 = 3 months
Definition of non-invasive diagnostics: exercise ECG, stress echocardiography, CT

and / or CT coronary calcification, cardio-MRI, myocardial scintigraphy, myocardial PET

Share of use decision support
Survey: Telephone patient survey on decision support (dichotomous, own question) in intervention and control group, each at T1 = 3 months

Joint decision-making on cardiac catheters
Survey: Telephone patient survey for joint decision-making (PEF-9) on the further

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Charité - Universitätsmedizin Berlin, Institut für Allgemeinmedizin, Berlin**
- other **Ruhr Universität Bochum, Abt. für Allgemeinmedizin, Bochum**
- other **Georg-August-Universität Göttingen, Universitätsmedizin (UMG),**
- other **Universitätsklinikum Würzburg, Medizinische Fakultät, Institut für Allgemeinmedizin, Würzburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/19**
- Target Sample Size: **1600**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients with chest pain / chest tightness, shortness of breath or similar symptoms for which you (recruiting doctors) are considering at least a distant cause of CHD;
Even patients who already have a CHD;
Even patients that you e.g. at V.a. seek acute coronary syndrome (home visit,

Exclusion criteria

Age <18 years,
Lack of knowledge of German

Addresses

- **Primary Sponsor**

  Philipps-Universität MarburgAbt. f. Allgemeinmedizin
  Mr. Prof. Dr Norbert Donner-Banzhoff
  Karl-von-Frisch-Str. 4
  35043 Marburg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **allgemeinmedizin at uni-marburg.de**
  URL: **https://www.uni-marburg.de/de/fb20/bereiche/methoden-**

- **Contact for Scientific Queries**

  Philipps-Universität Marburg
  Mr. Prof. Dr. med. Norbert Donner-Banzhoff
  Karl-von-Frisch-Str. 4
  35043 Marburg
  Germany

  Telephone: **06421/2865120**
  Fax: **06421/2865121**
  E-mail: **allgemeinmedizin at uni-marburg.de**
  URL: **https://www.uni-marburg.de/de/fb20/bereiche/methoden-**

- **Contact for Public Queries**

  Philipps-Universität Marburg
  Mr. Prof. Dr. med. Norbert Donner-Banzhoff
  Karl-von-Frisch-Str. 4
  35043 Marburg
  Germany

  Telephone: **06421/2865120**
  Fax: **06421/2865121**
  E-mail: **allgemeinmedizin at uni-marburg.de**
  URL: **https://www.uni-marburg.de/de/fb20/bereiche/methoden-**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and**

  Innovationsfonds des GBA
  53227 Bonn
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **https://innovationsfonds.g-ba.de/innovationsausschuss/**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2020/05/31**
- Number of Participants in Germany after Recruiting complete: **239**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **239**

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*