### Trial Description

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>The Sexuality of Patients in Rehabilitation of cardiovascular problems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Acronym</strong></td>
<td>SPARK</td>
</tr>
<tr>
<td><strong>URL of the trial</strong></td>
<td>[---]*</td>
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<tr>
<td><strong>Brief Summary in Lay Language</strong></td>
<td>Assuming an association between cardiovascular diseases and sexual disorders we conduct a survey in patients of several rehabilitation centres that offer treatment of cardiovascular diseases.</td>
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</tbody>
</table>
| **Brief Summary in Scientific Language** | Study design: Epidemiological cross-sectional study  
Background: Because of the pathophysiological correlative of an endothel damage in cardiovascular diseases as well as in sexual dysfunctions, especially in erectile dysfunction, a high prevalence of sexual dysfunctions in patients in the cardiovascular rehabilitation is supposed. Systematic surveys are missing in the literature so far.  
Methods:  
Sample: All German speaking patients of the participating rehabilitation clinics (planned 6) who are treated during the study and give informed consent.  
Study period: 09/04 - 02/05  
Expected number of participants: 2000  
Instruments: Self-assessment health questionnaires containing the Partnership Questionnaire (PFB), Derogatis Sexual Function Inventory (DSFi), Female Sexual Function Index (FSFI-d), International Index of Erectile Function (IIEF-15), Client Satisfaction Questionnaire (ZUF-8), Visual Analogue Scale (VAS), SF-36, Hospital Anxiety and Depression Scale (HADS), Alcohol Use Disorders Identification Test (AUDIT)  
Statistical Analyses: We perform an epidemiological descriptive analysis that offers representative conclusions about the population of cardiovascular patients in rehabilitation due to the high expected number of included patients and the selection criteria.  
Description focuses on:  
epidemiology of sexual dysfunctions of inpatients with cardiovascular diseases |
who are treated in rehabilitation clinics.

sexual life and sexual experience of patients and their partners, including satisfaction, wishes and expectations

sexuality-related anxieties

former information / former treatments

need for information and / or treatment of sexual dysfunctions as well as type of information brokering

In addition to the descriptive survey an explorative analysis is planned which investigates the association of particular patient characteristics with the prevalence of sexual dysfunctions. A binary logistic regression analysis with the existence / absence of sexual dysfunction as dependent variable is planned. Confounding with the following variables will be tested: course of disease, sex, age, family status, concomitant diseases. Interval-scaled, not normally distributed variables will be logarithmically transformed.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000022**
- Date of Registration in DRKS: **2008/09/05**
- Date of Registration in Partner Registry or other Primary Registry: **2005/03/15**
- Investigator Sponsored/Initiated Trial (IST/IIT): [---]*
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **181/04 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF000343 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- Free text: **sexual dysfunctions**
Interventions/Observational Groups

- Arm 1: Epidemiological descriptive analysis of a self-assessment health questionnaires

Characteristics

- Study Type: Non-interventional
- Study Type: Non-Interventional: Observational study
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Basic research/physiological study
- Assignment: Single (group)
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

An explorative analysis which investigates the association of particular patient characteristics with the prevalence of sexual dysfunctions. A binary logistic regression analysis with the existence / absence of sexual dysfunction as dependent variable is planned. Confounding with the following variables will be tested: course of disease, sex, age, family status, concomitant diseases.

Secondary Outcome

[---]*

Countries of recruitment

- DE Germany

Locations of Recruitment

Recruitment
Inclusion Criteria

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

Additional Inclusion Criteria

all German speaking patients of the participating cardiovascular rehabilitation clinics

Exclusion criteria

not German speaking, illiteracy

Addresses

Contact for Scientific Queries

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Sources of Monetary or Material Support

- Commercial (pharmaceutical industry, medical engineering industry, etc.)
  
Pfizer GmbH
  Karlsruhe
  Germany

  Telephone: [---]*
  Fax: [---]*
  E-mail: [---]*
  URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2006/01/31

Trial Publications, Results and other documents

- Paper Kristen L, Günzler C, Agyemang A, Berner MM. Effect of sexual function on health-related quality of life mediated by depressive symptoms in cardiac
rehabilitation. Findings of the SPARK project in 493 patients. The Journal of Sexual Medicine. Accepted for publication.

* 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.