

Trial Description

Title

Fear of coronary artery bypass surgery: What do patients experience as helpful?

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Fear is experienced by every patient who faces aortocoronary bypass surgery. Severe fear burdens not only patients but causes uncertainties for significant others, nurses, and physicians. Patients with depressions and anxiety before the operation have lower quality of life and higher complication rates afterwards. The project aims at the effectiveness of an short-term intervention with regard to the fear experienced before aortocoronary bypass surgery.

Brief Summary in Scientific Language

The aortocoronary bypass surgery is an anxiety-provoking biographic event. The study aims at the effectiveness of an short-term intervention with regard to the fear experienced before aortocoronary bypass surgery. In the first part of the study, sources for fears, coping strategies, and role of significant others and nurses are explored. The results are used to develop a screening tool for the second part of the study. There, the patients are randomized to an interventional and a control group. The intervention consists of a dialog with information and emotional support.

Organizational Data

- DRKS-ID: **DRKS00000696**
- Date of Registration in DRKS: **2011/01/19**
- Date of Registration in Partner Registry or other Primary Registry: **2007/06/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **175/07** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF001262 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- Free text: **fear of aortocoronary bypass operation**

Interventions/Observational Groups

- Arm 1: **dialog (30 min) with information on surgery and postoperative care and with emotional support with respect to the specific fears of the patient by a trained nurse**
- Arm 2: **no extended communication**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

change in situational fear before the operation before and after intervention (STOA-S, linear fear scale)

Secondary Outcome

- **anxiety (STOA-S, anxiety scale) after surgery (in-hospital before discharge and after 3 months)**
- **duration of postoperative ventilation (documentation of intensive care unit)**
- **postoperative pain (utilization of drugs, entries in case report forms, in-hospital before discharge)**
- **retrospective assessment of preoperative anxiety (in-hospital before discharge and after 3 months)**
- **change of STOA-T after 3 months**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/06/01**
- Target Sample Size: **170**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- **planned aortocoronary bypass grafting, also combined with valve surgery and / or MAZE**
- **first aortocoronary bypass operation**
- **at least 18 years old**
- **ability to communicate (knowledge of the German language, comprehension of the study, appropriate answers to the questions)**
- **written consent**

Exclusion criteria

most severe physical and mental burden due to the illness

Addresses

- **Primary Sponsor**

Universitätsklinik für Psychiatrie und Psychosomatik - Psychosomatische Medizin und Psychotherapie

Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

**Deutsche Stiftung für Herzforschung
Vogtstraße 50
60322 Frankfurt am main
Germany**

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Fax: **069 955128-313**

E-mail: **forschung at herzstiftung.de**

URL: **<http://www.dshf.de/index.php>**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/04/30**

Trial Publications, Results and other documents

* *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.*