Trial Description

Title

Influence of the implementation of an interdisciplinary tumorconference of integrative oncologie on the treatment of oncological patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

At the Ludwig Heilmeyer Tumour Centre CCCF cancer patient treatment is already discussed in interdisciplinary conferences called tumor boards. In these conferences, the attending medical diagnostic departments and the departments are represented as decision-makers. The tumor boards are an important component in the course of the treatment of patients.
As part of the research project, a new tumor board for integrative oncology will be established. In the integrative oncology tumor board, representatives from the most frequently used fields of complementary medicine, such as traditional Chinese medicine (TCM), Mind-body medicine, herbal medicine, exercise and breathing therapy will take part. Members of medical oncology care and supportive treatment facilities, such as the psycho-oncology, palliative care, nutritional medicine will be present.
Goal is to coordinate and integrate complementary medicine, supportive therapies into the standard oncology therapy.
Prior to the establishment of integrative oncology tumor board (TiO) and 6 months after the introduction, 300 oncology patients at the University Hospital of Freiburg are interviewed by questionnaires about their treatment satisfaction and their use of complementary medicine. In a follow up patients who are presented in the integrative oncology tumor board are interviewed before and after the performance in the TiO by questionnaire.
Through the introduction of the TIO complementary medical procedures and supportive therapies are better integrated into the oncological therapy.

Brief Summary in Scientific Language

Cross-sectional study: change in patient satisfaction and provide general information to patients about complementary medicine and the use of complementary medicine before and 6 months after the introduction of TiO, using a questionnaire survey
Intervention. Establishment of integrative oncology tumor boards
Longitudinal study: change in patient satisfaction after the introduction of TiO, using a questionnaire before and 3 months after presentation in the TiO.

So far given representation of the relationship between socio-demographic data

such as height, weight, educational level, living conditions, tumor-related patient data, strain and treatment data, date of tumor board idea, question, reason for presentation, tumor board decision and patient satisfaction.

Organizational Data

- DRKS-ID: **DRKS00003294**
- Date of Registration in DRKS: **2011/10/10**
- 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.: **369/11 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Cancer**
- ICD10: **C18 - Malignant neoplasm of colon**
- ICD10: **C20 - Malignant neoplasm of rectum**
- ICD10: **C50 - Malignant neoplasm of breast**
- ICD10: **C51 - Malignant neoplasm of vulva**
- ICD10: **C52 - Malignant neoplasm of vagina**
- ICD10: **C55 - Malignant neoplasm of uterus, part unspecified**
- ICD10: **C56 - Malignant neoplasm of ovary**
- ICD10: **C61 - Malignant neoplasm of prostate**
- ICD10: **C90 - Multiple myeloma and malignant plasma cell neoplasms**
- ICD10: **C91 - Lymphoid leukaemia**
- ICD10: **C92 - Myeloid leukaemia**
- ICD10: **C93 - Monocytic leukaemia**
- ICD10: **C94 - Other leukaemias of specified cell type**
- ICD10: **C95 - Leukaemia of unspecified cell type**

Interventions/Observational Groups

- Arm 1: **Survey of 300 cancer patients with a questionnaire over a period of 4 months; establishment of a tumor board integrative oncology. After 6 months duration survey of 300 cancer patients using a questionnaire.**

Characteristics

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

Primary Outcome

The first main objective of the study is to measure the effect of the establishment of an integrative oncology tumor board on the patients' satisfaction concerning the:
a) medical care provided by the University Hospital Freiburg (UKF)
b) complementary medical care at the UKF
c) involvement in decision making

The second main objective is measure the influence of the establishment of an integrative oncology tumor board on the general information of patients about complementary medicine and the use of complementary medicine.
All measurement are done with questionnaires.
First endpoint is after 5 months, the second after 16 months.

Secondary Outcome

Of further interest are
a.) the typical sources of information for complementary medicine
b.) its impact on communication with patients about the existing tumor boards
c.) change of use of complementary medicine
In the long term, a comparison is being considered in survival time, which can be done in a Follow up study.
Regardless of the introduction of integrative oncology tumor board the influence of various factors like the patient's gender, age, their education, the tumor entity and stage of the tumor on the use of complementary medicine will be examined.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/10/17**
- Target Sample Size: **750**
- 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

In the cross-sectional study all patients are included who have a tumor as a secure main diagnostic and have been in an organ center (breast center, gynecologic oncology, intestine center, prostate center, or leukemia center) at the University Hospital of Freiburg, and had 8 weeks before a treatment decision or were previously presented in a tumor board. To get sufficient homogeneity after stratification into the groups , only patients are interviewed who have received the following diagnoses: colorectal cancer, prostate cancer, breast cancer, gynecological tumors or leukemia.
In these highly prevalent tumor entities is a long-term therapy possible because they have a longer survival time. This ensures that the patients could benefit from the introduction of integrative oncology tumor boards.

In the longitudinal study cancer patients are included who will be presented in the integrative oncology tumor board because they would like to have a complementary medical treatment decision or need a second opinion or need a recommendation as the therapeutic treatment must be changed.
This can be oncology patients from the outpatient clinic for naturopathy or oncology patients from the outpatient departments or other cancer patients from the wards of University Hospital in Freiburg.

Exclusion criteria

Excluded are patients who are not powerful in the use of the German language or for other reasons are unable to complete the questionnaires.
All patients who are younger than 18 years.
Lack of consent.

Addresses

- **Primary Sponsor**

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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 Research (BMBF), etc.)**

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  Nachwuchsakademie Versorgungsforschung B-W
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- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/04/29**

Trial Publications, Results and other documents

- Abstract **11.Kongress für Versorgungsforschung**

** 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.*