Trial Description

Title

A prospective, controlled, multicentre non-interventional study of parenteral nutrition within the oncological outpatient care

Trial Acronym

COM3CB

URL of the trial

http:///

Brief Summary in Lay Language

Patients suffering from cancer often receive all essential nutrients via the vein. In general, there are two possibilities for this so called parenteral nutrition: Firstly, there are standardised nutritional solutions with all essential nutrients filled in three-chamber bags. As the name implies, these three-chamber bags consist out of three different chambers: one for carbohydrates, one for proteins and one for fats. Secondly the essential nutrients can be mixed individually for each patient in a one-chamber bag. It is not known yet, whether the choice of the bag influences the quality of life and the nutritional status of the patients. So this is the research question of this project.

Brief Summary in Scientific Language

The purpose of this non-interventional study is to compare the influence of standardised three-chamber bags and patient individual compounded bags on health-related quality of life and on nutritional status within oncological outpatient care.

Organizational Data

- DRKS-ID: **DRKS00010078**
- Date of Registration in DRKS: **2016/07/25**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **feki Code 016/1553 , Freiburger Ethik-Kommission International**

Secondary IDs

Health condition or Problem studied

- ICD10: **C00-C97 - Malignant neoplasms**

Interventions/Observational Groups

- Arm 1: **Patients who match the inclusion and exclusion criteria and who receive standardized parenteral nutrition (three-chamber bags) are observed in arm 1.**
- Arm 2: **Patients who match the inclusion and exclusion criteria and who receive individualised parenteral nutrition (compounding) are observed in arm 2.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Health Related Quality of Life is assessed by means of the questionnaires EORTC QLQ-C30 and German HPN-QOL®. The questionnaires are filled in at the beginning of the observation, app. 8 weeks later and again app. 12 weeks after beginning the observation, if the patient still receives a parenteral nutrition at this time.

Secondary Outcome

The Nutritional Status as secondary outcome is represented by five secondary endpoints:
- Malnutrition Universal Screening Tool (MUST)
- Body Weight
- Body Mass Index
- Albumin (as far as collected)
- Bioelectrical Impedance Analysis (as far as carried out)

The dates of documentation are the same as for HR-QoL: Baseline, after app. 8

weeks and, if the patient still receives parenteral nutrition, after app. 12 weeks.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Nordrhein-Westfalen**
- Doctor's Practice **Nordrhein-Westfalen**
- Doctor's Practice **Bayern**
- Doctor's Practice **Thüringen**
- Doctor's Practice **Thüringen**
- Doctor's Practice **Thüringen**
- Doctor's Practice **Thüringen**
- Doctor's Practice **Mecklenburg-Vorpommern**
- Doctor's Practice **Niedersachsen**
- Doctor's Practice **Brandenburg**
- Doctor's Practice **Sachsen Anhalt**
- Doctor's Practice **Nordrhein-Westfalen**
- Doctor's Practice **Nordrhein-Westfalen**
- Doctor's Practice **Bayern**
- Doctor's Practice **Thüringen**
- Medical Center **Thüringen**
- Doctor's Practice **Sachsen**
- Doctor's Practice **Sachsen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/10/14**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

**Total parenteral nutrition,
outpatient care,
ICD-10-GM C00-C97: Malignant neoplasms**

Exclusion criteria

**- Inpatient care during observation period
- Remaining life expectancy < 70 days 10 respectively 10 weeks
- Terminal phase
- Mental and behavioural disorders (ICD-10-GM F00 – F99)
- Noninfective enteritis and colitis (ICD-10 GM K50 - K52)
- Short bowel syndrome (ICD-10-GM K91.2)
- Human immunodeficiency virus [HIV] disease
(ICD-10-GM B20 – B24)
- Parenteral nutrition with standardised three-chamber bags not possible due to medical reasons
- Parenteral nutrition with individually compounded bags not possible due to medical reasons
- Parenteral nutrition at an earlier time
- cognitive deficits or insufficient speech comprehension
- Non-compliance
- Participation in a nutritional medical intervention study
- Missing written informed consent**

Addresses

- **Primary Sponsor**

  **GHD GesundHeits GmbH Deutschland
  22926 Ahrensburg
  Germany**

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

- **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

GHD GesundHeits GmbH Deutschland
22926 Ahrensburg
Germany

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

Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): **[---]***

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.*