Trial Description

Title

Evaluation of nutritional status in traumatology patients at the BG Trauma Center Tübingen

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Within the last years, the nutritional status of hospitalized patients as a part of patient care received more and more attention. Various studies in different disciplines have already shown malnutrition rates of more than 30% of all patients. In the field of orthopedics and trauma surgery there is still a lack of data. Therefor we want to evaluate the nutritional status of our hospitalized patients by a questionnaire. The consequences of possibly existing malnutrition on clinical outcome should be investigated.

Brief Summary in Scientific Language

A quarter of all hospitalized patients in Germany can be expected from an existing malnutrition. In internal medicine clinic patients with inflammatory bowel disease , chronic heart failure and benign lung diseases prevalence rates of malnourished patients of over 30% were observed. Risk factors for developing nutritional deficiencies were defined as: older age, alone living patients and low educational level. Relationships between a reduced nutritional status and increased complication rates and longer hospitalizations were demonstrated in clinical studies of different medical specialties. If malnutrition in patients of the Department of Orthopaedics and Traumatology exists and if malnutrition has an influence on the clinical outcome of traumatology patients is not known. Based on the available studies by other departments (urology, gynecology and internal medicine), a malnutrition rate of 15-30% and higher complication rates can be expected. The aim of this prospective clinical study , is the descriptive evaluation of nutritional status in traumatology patients at the BG Trauma Center Tübingen. The influence of malnutrition on the clinical outcome should be investigated.

Organizational Data

- DRKS-ID: **DRKS00006192**
- Date of Registration in DRKS: **2014/05/30**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **193/2014BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1157-2732**

Health condition or Problem studied

- Free text: **Different diagnosis in the field of orthopedics and traumatology**

Interventions/Observational Groups

- Arm 1: **Hospitalized traumatology patients at the BG Trauma Center Tübingen will be interviewed with a special questionnaire at 3 time points: time of hospitalization, 8 weeks follow-up, 6 months follow-up.**

Characteristics

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

Primary Outcome

Malnutrition of hospitalized patients at the time of hospitalization, during 8 weeks and 6 months follow-up (in%). Malnutrition is defined as NRS ≥ 3.

Secondary Outcome

- Malnutrition Assessment by MNA-Score (timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- complication rate (timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Duration of hospital stay
- Possibility oh physiotherapeutic mobilization
- Occupational changes (REFA-Classification; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Subjective health related quality of life (SF-36; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Regular healing processes (BG Data Assessment Score; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Definition of risk groups for malnutrition
- Changes of nutritional status after hospitalization (NRS, FOOD2013, MNA; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Consumption of defined food groups (FOOD2013; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Definition of Advantages for the Screening tools (MNA, NRS, FOOD2013; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)
- Definition of parameters that give a note to malnutrition (MNA, NRS, FOOD2013, BG data assessment score; timepoints: hospital stay, 8 weeks follow-up, 6 months follow-up)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Berufsgenossenschaftliche Unfallklinik Tübingen, Tübingen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/06/01**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Consent of the patient
- Patient receives a inpatient treatment at the BG Trauma Center Tübingen

Exclusion criteria

- No consent of the patient
- Patient is treated in an outpatient basis
- The survey is a too great burden for the patient (health status)
- The survey is not possible due to the lack of language skills
- Patient has a diagnosed dementia and the survey is not possible via the legal representative of the patient

Addresses

- **Primary Sponsor**

Siegfried Weller Institut für unfallmedizinische Forschung der Berufsgenossenschaftlichen Unfallklinik Tübingen
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

■ Recruitment Status: **Recruiting planned**

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- 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.*