PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Symptom Experience of Multiple Myeloma Patients Treated with Autologous Stem Cell Transplantation Following High Dose Chemotherapy

Trial Acronym

syMMex

URL of the trial

[---]*

Brief Summary in Lay Language

Aim of this study is to describe the symptoms of multiple myeloma patients during high-dosed chemotherapy and autologous stem cell transplantation. This is done at four time points: before the high dose, at the time of the greatest immuno defensive weakness, before discharge, and one month after discharge.

Brief Summary in Scientific Language

Background: Every year, about 1,300 autologous stem cell transplantations (ASCT) are performed in patients diagnosed with Multiple Myeloma (MM) in Germany. Symptoms related to this treatment are experienced as most severe by hematological patients. Most questionnaires used to assess symptom experience in this population offer a pre-selected choice of symptoms and do not measure all dimensions of symptom experience. Because of too heterogenous samples, little is known about the specific symptoms of patients with MM and ASCT. Aims of this study are to describe symptom experience of MM patients following high-dose chemotherapy (HD) and ASCT, to explore differences in symptom experience during HD and ASCT in patients with different induction and mobilization therapies, and to pilot-test the questionnaire of the "Patient Reported Outcomes in view of symptom experience of late effects and self-management of adult long-term survivors after allogeneic hematopoietic stem cell transplantation" (PROVIVO) study in an adapted version for the autologous transplant cohort. Methods: In a descriptive, longitudinal study at the Department of Hematology/Oncology, University Medical Center, Freiburg, 40 patients with MM, HD and ASCT will be included and asked to answer the PROVIVO questionnaire at admission, nadir, discharge and 30 days after discharge between September 2012 and April 2013.

Organizational Data

- DRKS-ID: **DRKS00004345**
- Date of Registration in DRKS: **2013/01/30**
- 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.: **339/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C90 - Multiple myeloma and malignant plasma cell neoplasms**

Interventions/Observational Groups

- Arm 1: **All Patients with multiple myeloma, 18 years of age and older admitted to one of the three transplant wards of the Department of Hematology/Oncology, University Medical Center, Freiburg, Germany, for HD and ASCT will be screened for inclusion criteria and consecutively included in the study. The criteria for inclusion are that the patients are able to read, understand, and answer the PROVIVO questionnaire and that HD and ASCT is part of the first treatment regimen after diagnosis. Patients have to answer the PROVIVO questionnaire at four timepoints:
admission (day -4, calculated from day of ASCT), nadir (moment of lowest count of white blood cells, about day +7 to +10), discharge (about day +15) and one month after discharge of HD and ASCT (30 days after discharge).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
-

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Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Symptom experience of patients will be measured with the PROVIVO questionnaire at four timepoints: admission (day -4, calculated from day of ASCT), nadir (moment of lowest count of white blood cells, about day +7 to +10), discharge (about day +15) and one month after discharge of HD and ASCT (30 days after discharge).

Secondary Outcome

Evaluation of the PROVIVO questionnaire for the use with patients with multiple myeloma and HD and ASCT

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Universitätsklinik Freiburg, Abteilung Hämatologie/Onkologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/01**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

All Patients with MM, and 18 years of age and older admitted to one of the three transplant wards of the Department of Hematology/Oncology, University Medical Center, Freiburg, Germany, for HD and ASCT will be screened for inclusion criteria and consecutively included in the study. The criteria for inclusion are that the patients are able to read, understand, and answer the PROVIVO questionnaire and that HD and ASCT is part of the first treatment regimen after diagnosis.

Exclusion criteria

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Addresses

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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 complete, follow-up complete**
- Study Closing (LPLV): **2015/07/31**

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.*