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

Trial Description

Title

High-dose chemotherapy and autologous stem cell transplantation in elderly primary CNS lymphoma patients - retrospective chart review

Trial Acronym

HDT-ASCT in elderly PCNSL

URL of the trial

[---]*

Brief Summary in Lay Language

Primary central nervous system lymphoma (PCNSL) is an aggressive Non-Hodgkin Lymphoma, which exclusively invades the central nervous system compartment at diagnosis. It accounts for 3% to 4% of all primary brain tumors and 4% to 6% of extra-nodal lymphomas. The incidence of PCNSL in immunocompetent patients has been steadily increasing over the last 30 years. Despite treatment improvement, the prognosis of PCNSL patients is still poor compared to systemic Non-Hodgkin Lymphoma. Patients older than 60 years account for 50% of all PCNSL cases. Although elderly patients are able to tolerate aggressive chemotherapy, they have an inferior prognosis compared to younger patients and are more seriously affected by iatrogenic toxicity; therefore they represent a unique treatment subgroup. High-dose chemotherapy followed by autologous stem cell transplantation has been shown to be feasible and highly effective in newly diagnosed eligible patients, but also in the salvage situation. Usually, this aggressive treatment approach is only offered to patients younger than 65 years of age. However, age alone may not be the only criterion to select patients for this effective treatment approach. In the present study, we plan to summarize feasibility, safety, and outcome of HCT-ASCT followed by ASCT in elderly PCNSL patients (> 65 years) treated at four different centers (Germany and United Kingdom) experienced in treating PCNSL patients.

Brief Summary in Scientific Language

Primary central nervous system lymphoma (PCNSL) is an aggressive Non-Hodgkin Lymphoma mostly of B-cell origin, which exclusively invades the central nervous system compartment at diagnosis. It accounts for 3% to 4% of all primary brain tumors and 4% to 6% of extra-nodal lymphomas. The incidence of PCNSL in immunocompetent patients has been steadily increasing over the last 30 years. High-dose methotrexate (HD-MTX) in combination with HD-cytarabine (HD-AraC) is the backbone of current treatment. A recent randomized controlled trial investigated the role of whole brain radiotherapy (WBRT) as consolidation therapy compared to no consolidation therapy, suggesting that WBRT does not prolong survival but enhances disease control. However, despite treatment improvement,

the prognosis of PCNSL patients is still poor compared to systemic Non-Hodgkin Lymphoma. Patients older than 60 years account for 50% of all PCNSL cases. Although elderly patients are able to tolerate aggressive systemic chemotherapy, they have an inferior prognosis compared to younger patients and are more seriously affected by iatrogenic toxicity, especially neurotoxicity following WBRT; therefore they represent a unique treatment subgroup. An US registry study of 579 elderly patients diagnosed with PCNSL in the 1990s revealed that the median survival was only 7 months and WBRT alone was the most common treatment modality (46%). High-dose chemotherapy with carmustine (BCNU) and thiotepa followed by autologous stem cell transplantation (ASCT) has been shown to be feasible and highly effective in newly diagnosed eligible patients, but also in the salvage situation. Usually, this aggressive treatment approach is only offered to patients younger than 65 years of age. However, age alone may not be the only criterion to select patients for this effective treatment approach. In the present study, we plan to summarize feasibility, safety, and outcome of HCT-ASCT followed by ASCT in elderly PCNSL patients (> 65 years) treated at four different centers (Germany and United Kingdom) experienced in treating PCNSL patients.

Organizational Data

- DRKS-ID: **DRKS00009037**
- Date of Registration in DRKS: **2015/08/17**
- 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.: **12/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C85.9 - Non-Hodgkin lymphoma, unspecified**

Interventions/Observational Groups

- Arm 1: **Investigation of outcome and feasibility of high-dose chemotherapy followed by autologous stem cell transplantation in elderly PCNSL patients.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**

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Study Type Non-Interventional: **Observational study**

- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Progression Free Survival (PFS)

Secondary Outcome

Remission status before HCT-ASCT
Adverse events during HCT-ASCT
Remission status after HCT-ASCT
Overall Survival (OS)

Countries of recruitment

- DE **Germany**
- UK **United Kingdom**

Locations of Recruitment

- University Medical Center **Innere Medizin I, Freiburg im Breisgau**
- Medical Center **Klinikum Suttgart, Stuttgart**
- Medical Center **Royal Marsden Hospital, London**
- Medical Center **Nottingham University Hospitals, Nottingham**
- Medical Center **Royal Free London NHS Trust, London**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/01**
- Target Sample Size: **24**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Immunocompetent patients with biopsy proven PCNSL who underwent HDT-ASCT, age at diagnosis >/=65 years

Exclusion criteria

Congenital or acquired immunodeficiency, age < 65 years

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*