B-CAP Hodgkins lymfom **Brentuximab armen**



Inklusionskriterier:	Ja	Nej
1: Histologically proven classical Hodgkin lymphoma		
2: First diagnosis, no previous treatment		
3: Age: 60 years or older		
4: Stage IA to IVB		
5: CIRS-G score of ≥ 7 or 4 in one organ system (except score 4 for eye, ear, nose and throat)		
6:Patients not eligible to curative poly-chemotherapy at the investigators judgment		
7: Voluntary written informed consent must be given before performance of any study-related procedure not part of standard medical care, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.		
8:Female patient is either post-menopausal for at least one year before the screening visit or surgically sterile or if of childbearing potential, agree to practice two effective methods of contraception, at the same time, from the time of signing the informed consent through six months after the last dose of study drug, or agrees to completely abstain from heterosexual intercourse.		
9:Male patients, even if surgically sterilized (i.e., status post vasectomy), agree to practice effective barrier contraception during the entire study period and through six months after the last dose of study drug, or agrees to completely abstain from heterosexual intercourse.		
10: Negative HIV test		
 11: Screening laboratory values must meet the following criteria: Hemoglobin ≥8.0 g/dl, WBC ≥1500/µl; neutrophils ≥1500/µl; platelets ≥75,000/µl (unless due to HL) Alkaline phosphatase <3 ULN, AST or ALT <3 ULN, serum total bilirubin <1.5 ULN (unless diagnosed with Gilbert's Syndrome)* INR 2 and an aPTT 2 ULN unless due to anticoagulation 		
12: Creatinine clearance > 40 ml/min as estimated by the Cockroft-Gault formula* * Cockcroft-Gault CrCl = (140-age) * (Wt in kg) * (0.85 if female) / (72 * Cr)		

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Eksklusionskriterier:	Ja	Nej
1: Composite lymphoma or nodular lymphocyte- predominant Hodgkin lymphoma (NLPHL)		
2: Prior chemotherapy or radiation for HL except prephase as outlined in the protocol		
3: Ongoing long-term (i.e. >6 months) ingestion of corticosteroids (e.g. for chronic polyarthritis) or antineoplastic drugs (e.g. methotrexate)		
4: Peripheral neuropathy greater than CTC Grade 1		
5: Female patient who are both lactating and breast-feeding or have a positive serum pregnancy test during the screening period or a positive pregnancy test on day 1 before first dose of study drug		
6: Any serious medical or psychiatric illness that could, in the investigator's opinion, potentially interfere with the completion of treatment according to the protocol		
7: Known cerebral or meningeal disease (HL or any other etiology), including signs or symptoms of PML		
8: Symptomatic neurologic disease compromising normal activities of daily living or requiring medications		
9: Any active systemic viral, bacterial, or fungal infection requiring systemic antibiotics within two weeks prior to first study drug dose		
10: Patients that have not completed any prior treatment chemotherapy and/or other investigational agents within at least five half-lives of last dose of that prior treatment		
11: Known hypersensitivity to recombinant proteins, murine proteins, or to any excipient contained in the drug formulation of brentuximab vedotin		
12: Known hepatitis B surface antigen-positive, or known or suspected active hepatitis C infection		
13: Diagnosed or treated for another malignancy within three years before the first dose or previously diagnosed with another malignancy and have evidence of residual disease. Patients with nonmelanoma skin cancer or carcinoma in situ of any type are not		

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Eksklusionskriterier:	Ja	Nej
excluded if they have undergone complete resection		
14: Patient's lack of accountability, inability to appreciate the nature, meaning and consequences of the trial and to formulate his/her own wishes correspondingly		
15: Non-compliance		
16: General intolerance of any protocol medication		
17: Patients who have a relationship of dependence or employer-employee relationship to the sponsor or the investigator		
18: Committal to an institution on judicial or official order		
19: Participation in another interventional trial that could interact with this trial		

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