A.O.U. Orbassano

Titolo:	R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥80 years, or frail ≥75 years – an open label randomized Nordic Lymphoma Group phase III trial - *NLG-LBC7 (POLAR BEAR)*
Patologia:	Diffuse large B-cell lymphoma
Tipo di Studio:	A randomized phase III open-label multicenter trial
Fase:	3
Principali criteri di inclusione:	1. Age ≥80 years or frail ≥75 years, according to simplified comprehensive geriatric assessment 2. Histologically confirmed lymphoma belonging to one of the following subtypes: a. diffuse large B-cell lymphoma, including transformation from an indolent lymphoma b. follicular lymphoma grade 3B c. T-cell/histiocyte-rich LBCL d. primary cutaneous DLBCL, leg type e. EBV-positive DLBCL, NOS f. primary mediastinal LBCL g. high grade B-cell lymphoma with MYC/BCL2 rearrangement 3. Stage II-IV disease 4. At least 1 measurable site of disease (>1.5 cm long axis) 5. No previous treatment for lymphoma 6. WHO performance status 0 – 3 (Grade 3 if related to DLBCL) 7. Written informed consent
Principali criteri di esclusione:	1. Severe cardiac disease: NYHA grade 3-4 2. CNS involvement at diagnosis 3. Uncontrolled serious infection 4. Impaired liver (transaminases > 3x normal upper limit or bilirubin > 1.5 x normal upper limit, unless due to Gilbert´s syndrome), renal (GFR<30ml/min) or other organ function not caused by lymphoma, which will interfere with the treatment 5. Absolute neutrophil count (ANC) <1000 cells/□L or platelets <100,000 cells/□L, unless due to lymphoma 6. Any other prior malignancy than non-melanoma skin cancer or stage 0 (in situ) cervical carcinoma, unless treated with curative intent, and without relapse since 2 years, or low grade prostate cancer, not in need of treatment 7. Psychiatric illness or condition which could interfere with their ability to understand the requirements of the study 8. Known hypersensitivity to rituximab, polatuzumab vedotin, cyclophosphamide, vincristine or doxorubicin, or to additives in the formulations above, or known hypersensitivity to other human, humanized, chimeric or porcine monoclonal antibodies, or

	HACA against rituximab 9. Peripheral neuropathy grade ≥ 2
Sede e contatti	Nordic Lymphoma Group represented by Region Skåne, Sweden