

Trial Synopsis

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Title of the study	<i>CHOP-14 (six cycles) ± alemtuzumab in Alk-negative T-lymphoma (Acronym: ACT)</i>
Indication	<i>Primary therapy of patients with Alk-negative T-NHL in patients aged 61 - 80 years</i>
Objectives	<i><u>Primary objective:</u> Improvement of the efficacy of chemotherapy with CHOP-14 by the additional use of the CD52 monoclonal antibody alemtuzumab measured on the basis of Event-free Survival. Comparison of +/- alemtuzumab addition concerning: further endpoints of efficacy, short term and long term side effects, adherence to protocol and withdrawal from therapy</i>
Interventions	<i>All patients will receive prephase treatment prior to initiation of therapy. Patients will be randomly assigned to receive six cycles chemotherapy with cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP-14) with G-CSF support with or without six doses of the monoclonal CD52 antibody alemtuzumab 30 mg s.c. on day 1 and 2 of CHOP each at 14-day intervals.</i>
Key inclusion and exclusion criteria	<i>Inclusions: patients with untreated peripheral T-cell lymphoma age 61-80 without major accompanying disorders Exclusions: cutaneous T-cell lymphoma, Alk-pos. T-cell lymphomas</i>
Outcomes	<i><u>Primary endpoint:</u> event-free survival (EFS) at 3 years <u>Secondary endpoints:</u> CR and OR rate, rate of primary progression, relapse rate, treatment-related deaths, overall survival free survival, tumour control, disease-free survival, protocol adherence, immune reconstitution after therapy</i>
Study design	<i>open-label, multicentre, prospective, randomised phase III study (treatment optimisation protocol)</i>
Statistical analysis	<i>Randomization at diagnosis with strata: study center, IPI-factors, bulk, histology Intent-to-treat analysis of treatment arms A and B by log rank test for EFS and multivariate analysis adjusting for prognostic factors</i>

Sample Size	<i>274 patients with peripheral T-cell lymphoma (137 per arm)</i>
Trial Duration	<i>First patient in: April 2007; last patient in: April 2011; Last patient out of treatment: October 2011; End of observation: October 2014; Duration of the entire trial: April 2007 to October 2014; Interim analysis October 2009</i>
Participating centers	<i>Trial group centers of the DSHNHL, NLG, HOVON, EORTC, NCRI, ALG, Polish, Austrian, Czech Lymphoma groups and further centers (see appendix)</i>
BMBF Project number	<i>GFVT 01014715</i>
EUDRA CT number	<i>2007-000821-23</i>