

2. PROTOCOL SYNOPSIS

TITLE	Efficacy of 6 courses CHOP plus Rituximab followed by myeloablative radiochemotherapy and autologous stem cell transplantation versus alternating courses of 3x CHOP and 3x DHAP plus Rituximab followed by a high dose ARA-C containing myeloablative regimen and autologous stem cell transplantation
SPONSOR	<i>European MCL Network</i>
STUDY DESIGN	Prospective, multicenter, randomized phase III study
INCLUSION CRITERIA	<ul style="list-style-type: none"> - patients < 65 years - advanced mantle cell lymphoma (Ann Arbor stage II-IV) according to the WHO classification - previously untreated - WHO performance status ≤ 2 or less - eligible for myeloablative therapy
TREATMENT	<p><i>standard arm:</i></p> <p>6 cycles CHOP plus Rituximab followed by myeloablative radiochemotherapy (12 Gray TBI, cyclo 2x 60 mg/m²) and autologous stem cell transplantation</p> <p><i>experimental arm:</i></p> <p>alternating cycles of 3x CHOP and 3x DHAP plus Rituximab followed by a high dose ARA-C containing myeloablative radiochemotherapy (10 Gray TBI, Ara-C, Melphalan) and autologous stem cell transplantation</p>
STRATIFICATION	<p><i>according to following factors:</i></p> <p>modified IPI score, study group</p>
STUDY OBJECTIVES	<p><i>Efficacy:</i></p> <p>Primary: Time to treatment failure</p> <p>Secondary: CR rate and overall survival, progression-free survival</p> <p><i>Safety:</i></p> <p>Adverse events, serious infectious complications</p>
NUMBER OF CENTERS	unlimited
NUMBER OF PATIENTS	360 (estimation of sequential test)
DURATION OF STUDY	4 years (estimation of sequential test)
ACTIVATION OF STUDY	15-06-2004

