

<b>Public Title</b>	High-dose melphalan and autologous SCT in relapsed AML
<b>Scientific Title</b>	High-dose melphalan with autologous stem cell transplantation in patients with relapsed acute myeloid leukemia (AML)
<b>Short Title</b>	HD-Melphalan
<b>Id KN/ELN</b>	LN_NN_2004_72
<b>Trialgroup</b>	NN
<b>Type of Trial</b>	multicentric
<b>Phase</b>	Phase II
<b>Disease</b>	Acute myeloid leukemia( AML) AML all subtypes without FAB M3
<b>Stage of Disease</b>	relapsed/refractory
<b>Aim</b>	<ul style="list-style-type: none"><li>- Evaluation of safety and tolerance of high-dose melphalan and autologous stem cell transplantation in relapsed AML-patients concerning hematological and non-hematological toxicity</li><li>- Evaluation of efficiency of therapy with high-dose melphalan and autologous stem cell transplantation on the basis of remission rate of relapsed AML</li><li>- Evaluation of efficiency of therapy with high-dose melphalan and autologous stem cell transplantation concerning event-free survival, time of remission and overall survival of the patient groups</li></ul>
<b>Outcomes</b>	<ul style="list-style-type: none"><li>- event-free survival</li><li>- time of remission</li><li>- overall survival (Primary Outcome)</li></ul>
<b>Inclusion Criteria</b>	<ul style="list-style-type: none"><li>- Relapse of AML after chemotherapy or autologous stem cell transplantation</li><li>- presence of a autologous graft, fetched during complete remission</li><li>- Duration of complete remission &gt; 2 month</li><li>- age &gt; 18 years</li><li>- patients general condition &lt; 2 according to ECOG performance scale</li><li>- confirmed contraception in fertile female patients</li><li>- written informed consent</li></ul>
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"><li>- severe concomittant diseases (clinically relevant heart failure, coronary sclerosis, chronic-obstructive lung disease, liver-, or kidney-dysfunction,</li><li>- active secondary malignancies (except: adaequately treated basalcell-carcinoma or squamous cell carcinoma of the skin and carcinoma in-situ of the cervix)</li><li>- general condition &gt; 2 according to ECOG performance scale</li><li>- Pregnant or breastfeeding women</li><li>- no informed consent</li></ul>
<b>Age</b>	>= 18 years
<b>Status</b>	No longer recruiting
<b>start of Recruitment</b>	05.04.2004
<b>Recruiting countries</b>	Germany
<b>Target Sample Size</b>	20

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<b>Interventions</b>	<ul style="list-style-type: none"><li>- melphalan</li><li>- autologous stem cell transplantation</li></ul>