

Scientific Title	Dendritic cells as autologous vaccine in patients with chronic myeloid leukemia
Short Title	CML Dendritic cells
Id KN/ELN	LN_EZIEXP_2001_96
Trialgroup	EZI-Expertengruppe
Type of Trial	single-group
Phase	Phase I
Disease	Chronic myeloid leukemia(CML) All subtypes
Stage of Disease	.
Inclusion Criteria	<ul style="list-style-type: none">- Curative options (e.g. allogeneic bone marrow transplantation) should not be available or should have been refused by the patient- Activity index of 0-2 according to WHO index or Karnofsky index > 60- Life expectancy > 3 months- Platelet count > 50.000/l and lymphocyte count > 1500/l- Ability to respond to recall antigens (as determined by skin test reactivity) should not be compromised- Informed consent- NB: Patients treated with interferon can only enter the study, if they failed to reach a major cytogenetic response after at least 12 months of interferon
Exclusion Criteria	<ul style="list-style-type: none">- Autoimmune disorders- Immunodeficiency syndromes- Known allergy to GM-CSF, TNF-, IL-4 or KLH (Keyhole Limpet Hemocyanin)- Pregnancy- Active infectious disease- Continuous therapy with corticosteroids or other immunosuppressive medications- Psychiatric disorders- Organ dysfunction, defined as follows:<ul style="list-style-type: none">- Thrombin time/partial thromboplastin time > 1.5 UNL- Creatinine > 2.0 mg/ml- Bilirubin > 3,0 mg/ml- ALAT/ASAT > 5 x UNL- Pulmonary dysfunction (dyspnea at rest or with minimal exertion)- Clinically relevant coronary heart disease or ventricular arrhythmia- Congestive heart failure > grade II NYHA
Age	All ages
Status	Closed
start of Recruitment	01.01.2001
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