European LeukemiaNet
SHORTPROTOCOL
CMPE Treosulfan + PBPCT in OMF

Scientific Title	Myeloablative conditioning of patients with myelofibrosis with myeloid metaplasia (MMM) using i.v. Treosulfan and autologous peripheral blood progenitor cell transplantation (PBPCT) with high doses of CD34+ cells
Short Title	CMPE Treosulfan + PBPCT in OMF
Id KN/ELN	LN_CMPEEX_2003_67
Trialgoup	CMPE-Expertengruppe
Type of Trial	multicentric
Phase	Phase II
Disease	Myeloproliferative disease(MPD) Myelofibrosis
Stage of Disease	.
Inclusion Criteria	- Male or female patients 18 years of age. - Patients with a confirmed diagnosis of MMM - Patients with high-risk disease - SGOT (ASAT) and/or SGPT (ALAT) not more than 2.5 x the upper limit of the normal range (ULN) at the laboratory where the analyses were performed. - Total serum bilirubin level not more than 1.5 x the ULN at the laboratory where the analysis was performed. - Serum creatinine concentration not more than 1.5 x the ULN at the laboratory where the analysis was performed. - Patients of childbearing potential must have a negative pregnancy test prior to the initiation of mobilization conditioning chemotherapy. Male and female patients agree to employ an effective barrier method of birth control throughout the study and for up to 3 months after autologous transplantation - Written voluntary informed consent.
Exclusion Criteria	- Patients receiving any other investigational agents within 28 days of day 1 of G-CSF mobilization. - Patients with grade 3/4 cardiac disease as defined by the New York Heart Association Criteria (Appendix 3) - Patients with a history of non-compliance to medical regimens or who are considered potentially unreliable - Patients with any serious concomitant medical condition which could, in the opinion of the investigator, compromise participation in the study - Female patients who are either pregnant or breastfeeding. Postmenopausal women must be amenorrheic for at least 12 months to be considered of non-childbearing potential - Patients who have senile dementia, mental impairment or any other psychiatric disorder that prohibits the patient from understanding and giving informed consent - Patients with known hypersensitivity to study medication.
Age	>= 18 years
Status	Closed
start of Recruitment	09.06.2003
Recruiting countries	Germany
Target Sample Size	24

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