

KURZPROTOKOLL **EURAMOS 1**

Öffentlicher Titel	Studie zur Behandlung von Kindern und Jugendlichen mit Osteosarkom
Wissenschaftl. Titel	A randomised trial of the European and American Osteosarcoma Study Group to optimize treatment strategies for resectable osteosarcoma based on histological response to pre-operative chemotherapy
Kurztitel	EURAMOS 1
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): Osteosarkom Kinder: Sarkome: Erstlinie
Ziele	- In a randomized trial, to examine whether the addition of ifosamide and etoposide (IE) to post-operative chemotherapy with cisplatin, doxorubicin and methotrexate improves event-free survival for patients with resectable osteosarcoma and a poor histological response to 10 weeks of pre-operative chemotherapy - In a randomized trial, to examine whether the addition of pegylated interferon α-2b (ifn) as a maintenance therapy after post-operative chemotherapy with cisplatin, doxorubicin and methotrexate improves event-free survival for patients with resectable osteosarcoma and a good histological response to 10 weeks of pre-operative chemotherapy - To investigate whether the addition of IE to post-operative therapy for poor responders, and the addition of ifn as maintenance therapy for good responders, leads to an improvement in the following outcomes: -Overall survival; -Short-term toxicity; - Long-term toxicity; -Quality of life - To investigate whether the addition of IE to post-operative therapy for poor responders, and the addition of ifn as maintenance therapy for good responders, leads to an improvement in event-free and overall survival in patients with localized osteosarcoma at entry. - To investigate whether biological or clinical correlates to histological response and outcome can be identified - To establish whether this international cooperation in clinical trials for osteosarcoma is feasible - To examine the outcome of the entire cohort of patients
Einschlusskriterien	- Histological evidence of high grade osteosarcoma of the extremity or axial skeleton including those arising as second malignancies - Resectable disease (defined as disease that is amenable or may become amenable to complete and potentially curative resection. Referral to a recognized specialist center may be appropriate) - Age ≤ 40 years at date of diagnostic biopsy - Registration within 30 days of diagnostic biopsy - Start chemotherapy within 30 days of diagnostic biopsy - Neutrophils $\geq 1,5 \times 10^9/L$ (or WBC $\geq 3 \times 10^9/L$ if neutrophils are not available) and platelet count $\geq 100 \times 10^9/L$ - Glomerular Filtration Rate $\geq 70 \text{ mL/min/1.73m}^2$ - Serum bilirubin $\leq 1,5 \times \text{ULN}$ - Sufficient cardiac function to receive anthracyclines: SF $\geq 28\%$ or EF $\geq 50\%$ - Adequate performance status (Karnofsky score ≥ 60 or WHO ≤ 2 for patients (age ≥ 16), Lansky score ≥ 60 (age ≤ 16). Patients whose performance status is adversely affected by a pathologic fracture but who are able to undergo treatment are eligible

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Ausschlusskriterien	- Patient fit to undergo protocol treatment and follow-up - Written informed consent - Unrespectable disease, primary or metastatic or both - Low grade osteosarcoma - Juxtacortical (periosteal, parosteal) osteosarcoma - Craniofacial osteosarcoma - Any previous treatment for osteosarcoma - Any previous chemotherapy for any disease - Any other medical condition precluding treatment with protocol chemotherapy (for example HIV, psychiatric disorder etc.) - Pregnant or lactating women
Alter	<= 40 Jahre
Förderer	Deutsche Kinderkrebsstiftung
Registrierung in anderen Studienregistern	EudraCT 2004-000242-20