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, dreiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): Osteosarkom Kinder: Sarkome: Erstlinie
Ziele	- In a randomized trial, to examine wether the addition of ifosamide and etopside (IE) to post-operative chemotherapy with cisplatin, doxorubicin and methotrexate improves event-free survival for patients with respectable 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 a-2b (ifn) as a maintenance therapy after post-operative chemotherapy with cisplatin, doxorubicin and methotrexate improves event-free survival for patients with respectable osteosarcoma and a good histological response to 10 weeks of pre-operative chemotherapy - To investigate whether the addition of IE tp post-operative therapy for poor responders, and the addition of ifn as maintenance therapy for good responders, leads to an improvment 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 improvment in event-free and overall survival in patients with localized osteosarcoma at entry. - To investigate whether biological or clinical correltaes to histological response and outcome can be identified - To establish whether this international cooperation in clinical trials for osteosarcoma is feasible - Tp 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 - Respectable 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 >= 1,5 x 10^9/L (or WBC >= 3 x 10^9/L if neutrophils are not availible) and platelet count >=100 x 10^9/L - Glomerular Filtration Rate >= 70mL/min/1.73m^2 - Serum bilirubin <=1,5 x ULN - Sufficant cardiac function to receive anthracyclines: SF >=28% or EF >= 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 - Patient fit to undergo protocol treatment and follow-up

	- Written informed consent
Ausschlusskriterien	- 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