

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	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- 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 \leq 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 $70\text{mL}/\text{min}/1.73\text{m}^2$- 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 \geq 60 or WHO \leq 2 for patients (age \geq 16), Lansky score \geq 60 (age \leq 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

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Ausschlusskriterien	<ul style="list-style-type: none">- 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