

## **KURZPROTOKOLL EURAMOS 1**

<b>Öffentlicher Titel</b>	Studie zur Behandlung von Kindern und Jugendlichen mit Osteosarkom
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	EURAMOS 1
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Muskeln/Bewegungsapparat: Knochenkrebs (Sarkome): Osteosarkom Kinder: Sarkome: Erstlinie
<b>Ziele</b>	<ul style="list-style-type: none"><li>- 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</li><li>- In a randomized trial, to examine whether the addition of pegylated interferon <math>\alpha</math>-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</li><li>- 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</li><li>- 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.</li><li>- To investigate whether biological or clinical correlates to histological response and outcome can be identified</li><li>- To establish whether this international cooperation in clinical trials for osteosarcoma is feasible</li><li>- To examine the outcome of the entire cohort of patients</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Histological evidence of high grade osteosarcoma of the extremity or axial skeleton including those arising as second malignancies</li><li>- 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)</li><li>- Age <math>\leq</math> 40 years at date of diagnostic biopsy</li><li>- Registration within 30 days of diagnostic biopsy</li><li>- Start chemotherapy within 30 days of diagnostic biopsy</li><li>- Neutrophils <math>\geq</math> <math>1,5 \times 10^9/L</math> (or WBC <math>\geq</math> <math>3 \times 10^9/L</math> if neutrophils are not available) and platelet count <math>\geq</math> <math>100 \times 10^9/L</math></li><li>- Glomerular Filtration Rate <math>\geq</math> <math>70\text{mL}/\text{min}/1.73\text{m}^2</math></li><li>- Serum bilirubin <math>\leq</math> <math>1,5 \times \text{ULN}</math></li><li>- Sufficient cardiac function to receive anthracyclines: SF <math>\geq</math> 28% or EF <math>\geq</math> 50%</li><li>- Adequate performance status (Karnofsky score <math>\geq</math> 60 or WHO <math>\leq</math> 2 for patients (age <math>\geq</math> 16), Lansky score <math>\geq</math> 60 (age <math>\leq</math> 16). Patients whose performance status is adversely affected by a pathologic fracture but who are able to undergo treatment are eligible</li><li>- Patient fit to undergo protocol treatment and follow-up</li></ul>

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<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Written informed consent</li><li>- Unrespectable disease, primary or metastatic or both</li><li>- Low grade osteosarcoma</li><li>- Juxtacortical (periosteal, parosteal) osteosarcoma</li><li>- Craniofacial osteosarcoma</li><li>- Any previous treatment for osteosarcoma</li><li>- Any previous chemotherapy for any disease</li><li>- Any other medical condition precluding treatment with protocol chemotherapy (for example HIV, psychiatric disorder etc.)</li><li>- Pregnant or lactating women</li></ul>
<b>Alter</b>	<= 40 Jahre
<b>Förderer</b>	Deutsche Kinderkrebsstiftung
<b>Registrierung in anderen Studienregistern</b>	EudraCT 2004-000242-20