

**KURZPROTOKOLL**  
**NB 2004**

<b>Öffentlicher Titel</b>	Kombinationschemotherapie, Radiotherapie und/oder auto-SZT bei Neuroblastom
<b>Wissenschaftl. Titel</b>	NB2004 Trial Protocol for Risk Adapted Treatment of Children With Neuroblastoma
<b>Kurztitel</b>	NB 2004
<b>Studienart</b>	multizentrisch, prospektiv, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Kinder: andere Tumorerkrankungen: Neuroblastom
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Neuroblastoma diagnosed according to the accepted criteria: histological diagnosis from tumor tissue or presence of distinct neuroblastoma cells in the bone marrow and elevated catecholamine metabolites (HVA, VMA) in blood or urine</li><li>- Either stage 4 and age <math>\geq 1</math>-21 years regardless of the MYCN-status, or stage 1-3/4S with MYCN-amplification and age <math>\geq 6</math>months - 21 years</li><li>- Informed consent of the guardians and - if appropriate for age and mental development - also of the patient</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Participation in other clinical trials wich might interfere with the interventions or outcome assessment of the NB2004-HR trial</li><li>- Pregnancy or lactation</li><li>- Insufficient contraception for girls in childbearing age. Only contraception with a Pearl index <math>\geq 1\%</math> are considered as sufficient. For the purpose of this trial, these are hormonal contraception (oral or dermal), long-term parenteral hormones, progesteron releasing implants, intramuscular progesterone, and IUD</li><li>- Any concomitant non-protocol anticancer therapy</li><li>- Incomplete inital staging</li></ul>
<b>Alter</b>	1 - 21 Jahre
<b>Fallzahl</b>	4
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<b>Förderer</b>	Deutsche Krebshilfe e.V.
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT00410631 (primäres Register)