

KURZPROTOKOLL
NB 2004

Öffentlicher Titel	Kombinationschemotherapie, Radiotherapie und/oder auto-SZT bei Neuroblastom
Wissenschaftl. Titel	NB2004 Trial Protocol for Risk Adapted Treatment of Children With Neuroblastoma
Kurztitel	NB 2004
Studienart	multizentrisch, prospektiv, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Kinder: andere Tumorerkrankungen: Neuroblastom
Einschlusskriterien	- 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 - Either stage 4 and age ≥ 1-21 years regardless of the MYCN-status, or stage 1-3/4S with MYCN-amplification and age ≥ 6 months - 21 years - Informed consent of the guardians and - if appropriate for age and mental development - also of the patient
Ausschlusskriterien	- Participation in other clinical trials which might interfere with the interventions or outcome assessment of the NB2004-HR trial - Pregnancy or lactation - Insufficient contraception for girls in childbearing age. Only contraception with a Pearl index $\geq 1\%$ are considered as sufficient. For the purpose of this trial, these are hormonal contraception (oral or dermal), long-term parenteral hormones, progesterone releasing implants, intramuscular progesterone, and IUD - Any concomitant non-protocol anticancer therapy - Incomplete initial staging
Alter	1 - 21 Jahre
Fallzahl	4
Förderer	Deutsche Krebshilfe e.V.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT00410631 (primäres Register)