KURZPROTOKOLL
PAED-201601 (MAKEI V)

Öffentlicher Titel	Phase III Studie zu Carboplatin vs Cisplatin bei extrakraniellen Keimzelltumoren
Wissenschaftl. Titel	Multizentrische prospektive Studie zu einem randomisierten Vergleich von Carboplatin mit Cisplatin bei extrakraniellen malignen Keimzelltumoren
Kurztitel	PAED-201601 (MAKEI V)
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Kinder: Keimzelltumoren
Einschlusskriterien	- Confirmed extracranial MGCT up to 17 11/12 years of age or patients with ovarian primaries up to 29 11/12 years of age on the date of written informed consent - Written informed consent prior to trial entry of parents and/or patient - Diagnosis of a chemotherapy-naïve extracranial MGCT - Karnofsky-Index of >70% or ECOG-Status 0-II - Negative pregnancy test within 7 days prior to start of treatment for female patients of childbearing potential, in case of ß-HCG secreting MGCT pregnancy has to be excluded by appropriate methods
Ausschlusskriterien	- Pregnancy - Lactation - Incomplete data at trial entry preventing risk group allocation - HIV-positivity - Live vaccine immunization within two weeks before start of protocol treatment - Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 12 months after end of chemotherapy - Current or recent (within 30 days prior to date of informed written consent) treatment with another investigational drug or participation in another interventional clinical trial, except trials with different end points than MAKEI V that can run in parallel to MAKEI V without influencing that trial, e.g., trials on antiemetics, antimycotics, antibiotics, strategies for psychosocial support, etc. - Any other medical, psychiatric or drug related condition, or social condition incompatible with protocol treatment. - Second malignancies - Negative preoperative tumour markers AFP and ß-HCG and solely pure teratoma histology - Known hypersensitivity against Cisplatin, Carboplatin, Etoposide, Ifosfamide or other ingredients of the medicinal product - Hearing impairment Grade 3 and 4 (CTCAE Vers.4.03)
Alter	0 - 80 Jahre
Prüfzentren	**Universitätsklinikum Frankfurt** (Aktiv) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main PD Dr. med. Konrad Bochennek konrad.bochennek@unimedizin-ffm.de
Gütesiegel	Deutsche Krebshilfe e.V.
Sponsor	Universitätsklinikum Bonn (Hauptsponsor)
Förderer	Deutsche Krebshilfe e.V.