KURZPROTOKOLL
Car2Brain

Öffentlicher Titel	Phase I-Studie mit intrakranieller Injektion von NK-Zellen bei rezidiviertem HER2-positivem Glioblastom
Wissenschaftl. Titel	Monozentrische, offene Phase I-Studie mit intrakranieller Injektion von NK-92/5.28.z (HER2.taNK) Zellen bei Patienten mit rezidiviertem HER2-positivem Glioblastom
Kurztitel	Car2Brain
Studienart	prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase I
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Zweitlinie oder höher
Einschlusskriterien	- Recurrent or refractory HER2-positive glioblastoma or its variant gliosarcoma in which a relapse surgery (partial or total) or a biopsy (patients with a biopsy are only eligible for the escalation cohort) is being planned. In patients with a planned biopsy, a maximum diameter of the contrast-enhancing lesion from which the biopsy will be done of 3 cm measured in the most recent magnetic resonance imaging at the time of enrollment to the study is allowed. - Prior therapy must include the standard of care for glioblastoma (radiotherapy plus concomitant and adjuvant chemotherapy with temozolomide according to the EORTC 26981 trial or at least a part thereof if the standard therapy was terminated prematurely due to therapy failure or poor tolerance). - Age >=18 years. - Life expectancy >= 3 months. - Bilirubin <= 3x normal, AST <= 5x normal, ALT <= 5x, serum creatinine <= 2x upper limit of normal for age, leukocyte count 3/nl, thrombocyte count 100/nl and Hb 8.0 g/dl. - Blood oxygenation of 90% as measured by pulse oximetry on room air. - Women must have a negative serum pregnancy test within 72h prior to the start of the first NK-92/5.28.z cell injection. - Sexually active patients must be willing to utilize effective birth control methods throughout the study and for 24 weeks after the last NK-92/5.28.z cell injection. This includes two different forms of effective contraception (e.g. hormonal contraceptive and condom, IUD/IUS and condom) or sterilization. - Patients should have been off other antineoplastic therapy for two weeks prior to entry in this study. Temozolomide will be allowed up to 48h preinjection. At the the time of inclusion, dexamethasone up to a total dose of 4 mg per day will be allowed if medically indicated. - Informed consent explained to and signed by patient; patient given copy of informed consent. - Karnofsky performance score of >= 50%.
Ausschlusskriterien	- Anti-angiogenic therapy e.g. with bevacizumab (Avastin®) in the last four weeks prior to study entry. - Coagulation disorder (INR>1.4 or PTT>50sec) or anticoagulation at therapeutic dosage. - Active autoimmune disease. - Patients with clinical or laboratory signs for immunodeficiency or under immunosuppressive medication other than corticosteroids. - Severe intercurrent infection. - Known HIV, HBV or HCV positivity. - Chronic heart failure NYHA >= III. - Patients with a prior solid organ transplantation or allogenic haematopoietic stem cell transplantation.

	- Unable to undergo MRI. - Pregnancy or breastfeeding. - Drug or alcohol abuse. - Severe psychiatric disorder which might interfere with the study treatment or examination. - Simultaneous participation in another clinical trial. If a subject participated in a trial testing another IMP, such IMP should have been terminated at least 30 days before inclusion of the subject.
Alter	18 Jahre und älter
Molekularer Marker	HER2/neu pos.
Prüfzentren	**Universitätsklinikum Frankfurt** (Aktiv) Dr. Senckenbergisches Institut für Neuroonkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Michael Burger Tel: 069 6301-87711 Fax: 069 6301-87713 michael.burger@kgu.de
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03383978 (primäres Register) EudraCT 2016-000225-39
Links	Weiterführende Informationen