KURZPROTOKOLL
NK-Immuntherapie: NSCLC-TKD/IL-2

Öffentlicher Titel	NK-Immuntherapie zur Behandlung von nicht-kleinzelligem Lungenkarzinom
Wissenschaftl. Titel	Targeted Natural Killer (NK) cell based adoptive immunotherapy for the Treatment of patients with Non-Small Cells Lung Cancer (NSCLC) after radiochemotherapy (RCT)
Kurztitel	NK-Immuntherapie: NSCLC-TKD/IL-2
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - sonstige Studien
Ziele	- To examine whether an adjuvant treatment with TKD/IL-2-activated, patient-derived NK cells following definitive RCT is feasible and effective. Comparison of progression -free survival between treatment and control group - To evaluate response to the treatment by comparing overall survival (OS), toxicity, quality of life (LCSS) between treatment and control group, and to determine biological parameters such as NK cell activation in the treatment group. Safety will be assessed according to NCI-CTC AE V4.0 criteria.
Einschlusskriterien	- First diagnose of histologically and/or cytologically proven and unresectable NSCLC with clinically stage III A and III B - Progression free according to RECIST criteria at the first assessment after completion of radiochemotherapy - Confirmed presence of Hsp70 on patient´s tumors - Female or male, age 18 to 75 years - ECOG Status <= 2 - Neutrophil count >= 1.5 x 109/l after completion of radiochemotherapy - WBC >= 2.5 x 109/l after completion of radiochemotherapy - Haemoglobin >8g/l after completion of radiochemotherapy - Platelet count >= 100 x 109/l after completion of radiochemotherapy - Normal renal function (creatinine <150% ULN) - Normal liver function (Bilirubin <150% ULN; G-GT, GPT und GOT <250% ULN;) - Normal blood coagulation (PTT 25-40s) - Measurable disease according to RECIST criteria - Female patients of childbearing potential must have negative pregnancy test performed during screening period (<= 14 days before initiation of study drug dosing). Postmenopausal women must be amenorrhea for at least 12 months to be considered of non-childbearing potential. Male and female patients of reproductive potential must agree to employ an effective method of birth control throughout the study and for 6 months following discontinuation of study drug. - Written (signed) Informed Consent document indicating that the patient (or legally acceptable representative) has been informed of all pertinent aspects of the trial prior to enrollment and to participate in the study - Ability to comply with study and follow-up procedures
Ausschlusskriterien	- Prior treatment with any other investigational drug within 4 weeks prior to first dose of study medication - Any severe heart disease or any severe concomitant disease (ECOG stage > 2) - Patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology - Patients that show ALK positivity or an activating mutation of the EGFR-TK domain

	- Any disease (including psychotic disorders, drug abuse, active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, serious cardiac arrhythmia requiring medication, hepatic, renal or metabolic disease), metabolic dysfunction, physical examination finding, or clinical laboratory finding likely (in the investigator's opinion) to affect the evaluation of the study or place the patient at risk whilst on treatment - Any serious infection or sepsis - Any active autoimmune disease - Any immunodeficiency syndrome - Surgery or immunotherapy within 4 weeks before study entry - Patients with known hypersensitivity to any of the administered substances should be excluded from the clinical trial - Patients with HIV infections as well as patients with positive Hepatitis A, B, C tests - Receipt of immunosuppressive drugs including systemic corticosteroids within 3 weeks before study entry - Radio-, cytostatic-, and immuno-therapy in parallel or within 2 weeks prior to study start - Women who are pregnant or breast feeding - Female patients of reproductive potential unwilling to practice a highly effective method of birth control - History of noncompliance with medical regimens - Patients unwilling to or unable to comply with the protocol
Alter	18 - 75 Jahre
Molekularer Marker	ALK wt HSPA4 (Hsp70) EGFR wt
Fallzahl	90
Prüfzentren	**Universitätsklinikum Frankfurt** (Rekrutierung beendet) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Atefeh Nateghian Tel: 069 6301-4655 Fax: 069 6301-4567 studien-strahlen@unimedizin-ffm.de Prof. Dr. med. Claus Rödel studien-strahlen@unimedizin-ffm.de
Sponsor	Technische Universität München (Hauptsponsor)
Förderer	Bundesministerium für Bildung und Forschung
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02118415 EudraCT 2008-002130-30
Therapie	This is an interventional phase I/II clinical trial incorporating a parallel control group of patients receiving no adjuvant immunotherapy. Patients with non-small lung cell carcinoma (NSCLC) in stage III A and III B will be enrolled into the clinical trial. The aim of the study is to show the efficacy of an adjuvant treatment with Hsp70-peptide TKD/IL-2 activated, autologous NK cells following completion of standard radiochemotherapy (Cisplatin/Vinorelbine). A preceeding clinical phase I trial showed an excellent safety profile for ex vivo TKD/IL-2 activated, autologous NK cells