KURZPROTOKOLL INTERSORTACE

Öffentlicher Titel	Phase II Studie zu Sorafenib mit transarterieller Chemoembolisation (TACE) bei Leberzellkarzinom
Wissenschaftl. Titel	Intermittent treatment with sorafenib in combination with transarterial chemoembolization (TACE) in hepatocellular carcinoma (HCC): a randomized open-label phase 2 study
Kurztitel	INTERSORTACE
Studienart	prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Erstlinie
Einschlusskriterien	- Written informed consent granted prior to initiation of any study specific screening procedures - Patients with histologically confirmed HCC not suitable for resection or liver transplantation (> 3 tumors > 3 cm; one tumor > 5 cm). Vascular invasion is allowed as long as the main trunk of the portal vein is not invaded) - Absence of extrahepatic spread - Age >=18 years - Patients with measurable disease according to RECIST - Performance status ECOG 0 and 1 (Appendix 20) - Patients naive to treatment with respect to the HCC - Normal organ and bone marrow function defined as: (a) Hematopoetic: absolute neutrophil count > 1,500/mm3, platelet count > 60,000/mm^3, hemoglobin > 9g/dL; (b) INR < 1.5 ULN; (c) Hepatic: AST or ALT < 5 x ULN, bilirubin <= 3 mg/dl; (d) Renal: serum creatinine < 1.5 x ULN; (e) Child-Pugh stage A - Hematopoetic: absolute neutrophil count > 1,500/mm3, platelet count > 60,000/mm3, hemoglobin > 9g/dL - INR < 1.5 ULN - Hepatic: AST or ALT < 5 x ULN, bilirubin <= 3 mg/dl - Renal: serum creatinine < 1.5 x ULN - Child-Pugh stage A - Women of childbearing potential must have a negative serum pregnancy test performed within 7 days prior to the randomization - Male or female patients of child-bearing potential must agree to use double-barrier contraceptive measures, oral contraception, or avoidance of intercourse during the study and for 90 days after last investigational drug dose received
Ausschlusskriterien	- Extrahepatic tumor manifestation - Thrombosis of the main portal vein (thrombosis of a side-branch is allowed) - Child Pugh status B or C > 6 points according to Child Pugh classification (Appendix 20) - Prior TACE or selective intraarterial Radiotherapiy (SIRT) - Prior systemic anticancer chemotherapy for HCC - Life expectancy of less than 12 weeks - Esophageal varices grade III (any) or esophageal varices grade II with increased risk for bleeding (red wale signs, cherry spots, red coloration, hematocystic spots) without prophylactic band ligation - Cardiac disease: congestive heart failure > class II NYHA (Appendix 20), unstable angina or new onset of angina or myocardial infarction within the past 6 months. Cardiac ventricular arrhythmias requiring antiarrhythmic therapy (> Grad 2 NCI-CTCAE Version 3.0)

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- Uncontrolled hypertension defined as systolic blood pressure > 150 mm Hg or diastolic pressure > 90 mm Hg, despite optimal management
- Known or suspected hyperthyroid state
- Patients with seizure disorder requiring medication (such as steroids or antiepileptics)
- History of organ allograft
- Active clinically serious infections > CTCAE grade 2 except chronic hepatitis C infection (Appendix 20)
- Thrombotic or embolic events including transient ischemic attacks within the past 6 months
- Hemorrhage/bleeding event >= CTCAE grade 3 within 4 weeks of first dose of study drug
- Acute variceal bleeding within the last 2 weeks
- Serious non healing wound, ulcer or bone fracture
- Evidence or history of bleeding diathesis or coagulopathy
- Therapeutic anticoagulation with Marcumar, heparins or indirect factor-Xa inhibitors or direct thrombinantagonists. Low dose aspirin is permitted (<=100 mg/day)
- Major surgery, open biopsy or significant traumatic injury within 4 weeks of first dose of study drug
- Known or suspected allergies to sorafenib, mitomycin C or lipiodol
- Previous cancer that is distinct in primary site or histology from HCC except cervical cancer in situ, treated basal cell carcinoma, superficial bladder tumors or any cancer curatively treated 3 years prior to study entry
- Substance abuse, medical or psychological condition that may interfere with the patient´s participation in the study
- Participation in another clinical trial with any investigational study drug (whatever the use, curative, prophylactic or diagnostic intent) within 30 days prior to enrollment
- Incapability to give valid informed consent (including patients who are dependent on the sponsor or the investigator)
- Pregnancy and breast-feeding women

Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 1** (Geschlossen) Gastroenterologie / Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Jörg Trojan Tel: 069 6301-87769 Fax: 069 6301-6580 joerg.trojan@kgu.de **Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik I, Gastroenterologie/Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Jörg Trojan Tel: 069 6301-87769 Fax: 069 6301-6580 joerg.trojan@kgu.de
Sponsor	Universität Frankfurt
Registrierung in anderen Studienregistern	EudraCT 2014-005406-38 Deutsches Register Klinischer Studien DRKS00012551

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