KURZPROTOKOLL
I4T-MC-JVDE

Öffentlicher Titel	Phase III Studie zu Ramucirumab in zweiter Linie nach Sorafenib-Behandlung bei Hepatokarzinom
Wissenschaftl. Titel	Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Ramucirumab and Best Supportive Care (BSC) Versus Placebo and BSC as Second-Line Treatment in Patients With Hepatocellular Carcinoma and Elevated Baseline Alpha-Fetoprotein (AFP) Following First-Line Therapy With Sorafenib
Kurztitel	I4T-MC-JVDE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Zweitlinie oder höher
Einschlusskriterien	- A diagnosis of HCC based on histopathologic findings, or a diagnosis of cirrhosis and a tumor with classical HCC imaging characteristics. - Prior sorafenib treatment for at least 14 days and discontinuation of sorafenib 14 days prior to randomization. - Radiographic disease progression during or after sorafenib therapy or discontinuation of sorafenib because of intolerance. - Sorafenib was the only systemic therapy for HCC. - 1 measurable lesion per Response Evaluation Criteria In Solid Tumors (RECIST) Version 1.1 that has not been previously treated with locoregional therapy. A participant with a lesion(s) that has previously been treated with locoregional therapy is also eligible, if the lesion has documented progression after locoregional treatment and is measureable. - Child-Pugh score <7 (Child-Pugh Class A). - Barcelona Clinic Liver Cancer (BCLC) Stage C disease or BCLC Stage B disease not amenable to locoregional therapy or refractory to locoregional therapy. - Baseline AFP 400 nanograms/milliliter. - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. - Resolution of all clinically significant toxic effects of prior therapy. - Total bilirubin 1.5 times upper limit of normal value (ULN), aspartate transaminase (AST) and alanine transaminase (ALT) 5 × ULN. - Surgically sterile, postmenopausal, or compliant with a highly effective contraceptive method. - If a woman of childbearing potential, a negative serum pregnancy test prior to randomization. - Willing to provide blood for research.
Ausschlusskriterien	- Fibrolamellar carcinoma or mixed hepatocellular cholangiocarcinoma. - Concurrent malignancy. Participants with carcinoma in situ of any origin and participants with prior malignancies in remission may be eligible with sponsor approval. - Previous brain metastases, leptomeningeal disease, or uncontrolled spinal cord compression. - History of or current hepatic encephalopathy or clinically meaningful ascites. - Ongoing or recent hepatorenal syndrome. - Liver transplant. - Previous systemic therapy with vascular endothelial growth factor (VEGF) pathway inhibitors other than sorafenib for treatment of HCC. - Hepatic locoregional therapy following sorafenib or within 28 days prior to randomization.

- Major surgical procedure, traumatic injury, non-healing wound, or peptic ulcer 28 days prior to randomization.
- Placement of a subcutaneous venous access device within 7 days prior to the first dose of study treatment unless the procedure is judged of low risk of bleeding.
- Enrolled in a clinical trial involving an investigational product or nonapproved use of a drug or in medical research judged not to be scientifically or medically compatible with this study.
- Discontinued from study treatment from another clinical trial within 28 days prior to randomization.
- Known allergy to any of the treatment components.
- Uncontrolled hypertension.
- Any arterial thrombotic event, including myocardial infarction, unstable angina, cerebrovascular accident, or transient ischemic attack, <6 months prior to randomization.
- Esophageal or gastric varices that require intervention or represent high bleeding risk. Participants with evidence of portal hypertension or prior bleeding must have had endoscopic evaluation within 3 months prior to randomization.
- Gastrointestinal perforation or fistulae within 6 months prior to randomization.
- Symptomatic congestive heart failure (New York Heart Association II-IV), unstable angina pectoris, or symptomatic or poorly controlled cardiac arrhythmia.
- Pregnant or breast-feeding.
- Any medical or psychiatric condition that may increase the risk associated with study participation or may interfere with the interpretation of study results. Conditions include but are not limited to:
- o Human immunodeficiency virus infection or acquired immunodeficiency syndrome-related illness.
- o Active or uncontrolled clinically serious infection. (Participants with chronic viral hepatitis are eligible.)
- o Ongoing or recent history of drug abuse.
- o Uncontrolled hereditary or acquired thrombotic or bleeding disorder.
- Bowel obstruction, history or presence of inflammatory enteropathy or extensive intestinal resection
- Therapeutic dose anticoagulation with warfarin, low molecular-weight heparin, or similar agents.
- Chronic therapy with nonsteroidal anti-inflammatory agents or other anti-platelet agents. Aspirin at doses up to 100 milligrams/day is permitted.

Alter 18 Jahre und älter

Fallzahl 399

Prüfzentren

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Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02435433 EudraCT 2014-005068-13