KURZPROTOKOLL
EORTC 1709

Öffentlicher Titel	Phase III Studie zu Marizomib bei neu diagnostiziertem Glioblastom
Wissenschaftl. Titel	Eine Phase-III-Studie von Marizomib in Kombination mit Temozolomid-basierter Standard-Radiochemotherapie im Vergleich zur Temozolomid-basierten Standard-Radiochemotherapie allein bei Patienten mit neu diagnostiziertem Glioblastom
Kurztitel	EORTC 1709
Studienart	prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie

Einschlusskriterien

- Histologically confirmed newly diagnosed glioblastoma (WHO grade IV)
- Tumor resection (gross total or partial), or biopsy only
- Availability of FFPE tumor block or 24 unstained slides for MGMT analysis
- Patient must be eligible for standard TMZ/RT + TMZ
- Karnofsky performance score (KPS) >= 70
- Recovered from effects of surgery, postoperative infection and other complications of surgery (if any)
- The patient is at least 18 years of age on day of signing informed consent
- Stable or decreasing dose of steroids for at least 1 week prior to inclusion
- The patient has a life expectancy of at least 3 months
- Patient has undergone a brain MRI within 14 days of randomization but after intervention (resection or biopsy)
- The patient shows adequate organ functions as assessed by the specified laboratory values within 2 weeks prior to randomization defined as adequate bone marrow, renal and hepatic function within the following ranges: WBC 3×10*9/L ANC 1.5×10*9/L Platelet count of 100×10*9/L independent of transfusion Hemoglobin 10 g/dl Total Bilirubin 1.5 ULN ALT, AST, alkaline phosphatase (ALP) 2.5 × ULN Serum creatinine < 1.5 x ULN or creatinine clearance (CrCl) > 30 mL/min(using the Cockcroft-Gault formula)
- Women of child bearing potential (WOCBP) must have a negative urine or serum pregnancy test within 7 days prior to the first dose of study treatment.
- Patients of childbearing / reproductive potential must agree to use adequate birth control measures, as defined by the investigator, during the study treatment period and for at least 6 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1 percent per year) when used consistently and correctly. Patients must also agree not to donate sperm during the study and for 6 months after receiving the last dose of study treatment.
- Women who are breast feeding must agree to discontinue nursing prior to the first dose of study treatment and until 6 months after the last study treatment.
- Ability to take oral medication
- Ability to understand the requirements of the study, provide written informed consent and authorization of use and disclosure of protected health information, and agree to abide by the study restrictions and return for the required assessments.
- Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.

Ausschlusskriterien

- Patients with known IDH mutation (IDH mutation testing should be considered for younger patients or patients with tumors with atypical features)
- Prior treatment for glioblastoma other than surgery; prior RT to brain and/or prior chemotherapy for lower grade glioma. Placement of BCNU wafer during surgery is not allowedl

- Planned additional treatment with Tumor-Treating Fields
- Known hypersensitivity to the active substance or any of the excipients in the IV formulation
- History of thrombotic or hemorrhagic stroke or myocardial infarction in past 6 months
- Congestive heart failure (New York Heart Association Class III to IV, see Appendix C), symptomatic ischemia, conduction abnormalities uncontrolled by conventional intervention, and myocardial infarction within 6 months prior to first dose
- Concurrent severe or uncontrolled medical disease (e.g., active systemic infection, diabetes, hypertension, coronary artery disease, psychiatric disorder) that, in the opinion of the investigator, would compromise the safety of the patient or compromise the ability of the patient to complete the study
- Known history or current evidence of active Hepatitis B (e.g., positive HBV surface antigen) or C (e.g., HCV RNA [qualitative] is detected) Known or current evidence of Human Immunodeficiency Virus (HIV) (positive HIV-1/2 antibodies) Prior or second invasive malignancy, except nonmelanoma skin cancer, completely resected cervical carcinoma in situ, low risk prostate cancer (cT1-2a N0 and Gleason score 6 and PSA < 10 ng/mL), either totally resected or irradiated with curative intent (with PSA of less than or equal to 0.1 ng/mL) or under active surveillance as per ESMO guidelines. Other cancers for which the subject has completed potentially curative treatment more than 3 years prior to study entry are allowed.
- Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

Alter 18 Jahre und älter

Prüfzentren

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