

KURZPROTOKOLL **EORTC 1608**

Öffentlicher Titel	Phase I Studie zu TG02 bei Gliomen Grad III und IV
Wissenschaftl. Titel	Study of TG02 in Elderly Newly Diagnosed or Adult Relapsed Patients with Anaplastic Astrocytoma or Glioblastoma: A Phase Ib Study (STEAM)
Kurztitel	EORTC 1608
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, dreiarmlig, Investigator Initiated Trial (IIT)
Studienphase	Phase I
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie Nervensystem: Gliome: WHO Grad II und Grad III - Erstlinie
Einschlusskriterien	<ul style="list-style-type: none">- Newly diagnosed glioblastoma or anaplastic astrocytoma, IDH1R132H-non-mutant by immunohistochemistry locally assessed, with FFPE tissue available for central MGMT testing and optional biomarker studies (treatment allocation will be performed based on centrally assessed MGMT result)- Tumor debulking surgery, including partial resection- Age > 65 and considered non-eligible for combination therapy (TMZ/RT -> TMZ) in Investigator's opinion- No prior RT with overlap of radiation fields with the planned RT in this study (Group A)- No prior therapy for glioblastoma or anaplastic astrocytoma before surgery Specifics for group C- IDH1R132H-non-mutant glioblastoma or anaplastic astrocytoma at first relapse with tissue available from first surgery- Diagnosis of recurrence more than 3 months after the end of RT for initial treatment- Intention to be treated with standard TMZ/RT -> TMZ for initial treatment (at least one dose of TMZ administered; RT alone or chemotherapy alone as initial treatment are not permitted)- No discontinuation of TMZ for toxicity during first-line treatment
Ausschlusskriterien	<ul style="list-style-type: none">- for groups A and B- Prior RT with overlap of radiation fields with the planned RT in this study (Group A)- Prior therapy for glioblastoma or anaplastic astrocytoma before surgery Specifics for group C- Discontinuation of TMZ for toxicity during first-line treatment- RT or stereotactic radiosurgery is not allowed for the treatment of first recurrence prior to enrollment in this study
Alter	18 Jahre und älter
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