

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
Sponsor	European Organization for Research and Treatment of Cancer
Förderer	Tragara Pharmaceuticals, Inc.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03224104 (primäres Register) EudraCT 2017-001029-42