# *KURZPROTOKOLL*
# *EORTC 1608*

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| **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, dreiarmig, Investigator Initiated Trial (IIT) |
| **Studienphase** | Phase I |
| **Erkrankung** | Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie<br>Nervensystem: Gliome: WHO Grad II und Grad III - Erstlinie |
| **Einschlusskriterien** | - 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)<br>- Tumor debulking surgery, including partial resection<br>- Age > 65 and considered non-eligible for combination therapy (TMZ/RT -> TMZ) in Investigator's opinion<br>- No prior RT with overlap of radiation fields with the planned RT in this study (Group A)<br>- No prior therapy for glioblastoma or anaplastic astrocytoma before surgery Specifics for group C<br>- IDH1R132H-non-mutant glioblastoma or anaplastic astrocytoma at first relapse with tissue available from first surgery<br>- Diagnosis of recurrence more than 3 months after the end of RT for initial treatment<br>- 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)<br>- No discontinuation of TMZ for toxicity during first-line treatment |
| **Ausschlusskriterien** | - for groups A and B<br>- Prior RT with overlap of radiation fields with the planned RT in this study (Group A)<br>- Prior therapy for glioblastoma or anaplastic astrocytoma before surgery Specifics for group C<br>- Discontinuation of TMZ for toxicity during first-line treatment<br>- RT or stereotactic radiosurgery is not allowedfor the treatment of first recurrence prior to enrollment in this study |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Universitätsklinikum Frankfurt** (Geschlossen)<br>Dr. Senckenbergisches Institut für Neuroonkologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Dr. med. Michael Burger<br>Tel: 069 6301-87711<br>Fax: 069 6301-87713<br>michael.burger@kgu.de |
| **Sponsor** | European Organization for Research and Treatment of Cancer |
| **Förderer** | Tragara Pharmaceuticals, Inc. |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03224104 (primäres Register)<br>EudraCT 2017-001029-42 |