ForPatients
by Roche

High Grade Glioma

A Study of Bevacizumab (Avastin) in Combination With Temozolomide (TMZ) and Radiotherapy in Paediatric and Adolescent Participants With High-Grade Glioma

Trial Status	Trial Runs In	Trial Identifier
Completed	14 Countries	NCT01390948 2010-022189-28 ITCC-019 HGG-01 BO25041

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II Open-Label, Randomized, Multi-Centre Comparative Study Of Bevacizumab-Based Therapy In Paediatric Patients With Newly Diagnosed Supratentorial, Infratentorial Cerebellar, or Peduncular High-Grade Glioma

Trial Summary:

This randomized, open-label, multicenter, 2-arm study will investigate the efficacy, safety, tolerability and pharmacokinetics of bevacizumab when added to postoperative radiotherapy with concomitant and adjuvant TMZ as compared to postoperative radiotherapy with concomitant and adjuvant TMZ alone in paediatric participants with newly diagnosed histologically confirmed World Health Organization (WHO) Grade III or IV localized supratentorial or infratentorial cerebellar or peduncular high grade glioma (HGG). Participants will be randomly assigned to one of two treatment arms. Upon approval by the Health Authorities/Ethics Committees in the participating countries, an additional young participant cohort (YPC) (children >/= 6 months and < 3 years of age with progressive or relapsed metastatic or localized, supra- or infratentorial, non-brain stem WHO Grade III or IV HGG) was included in the study. Children in the YPC will receive bevacizumab and TMZ without radiation therapy. The anticipated time on study treatment is over 1 year.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#6 Months & # 18 Years	No

Inclusion Criteria:

Inclusion Criteria - Main cohort :

- Paediatric participants, aged >= 3 years and < 18 years
- Written informed consent obtained from the participant/parents or legally acceptable representative
- Newly diagnosed localised, supratentorial or infratentorial cerebellar or peduncular, WHO Grade III or IV gliomas
- Local histological diagnosis confirmed by a designated central reference neuropathologist
- Availability of the baseline magnetic resonance imaging (MRI) performed according to imaging guidelines
- Able to commence trial treatment not before 4 weeks after cranial surgery and no later than 6 weeks following the last major surgery
- Adequate bone marrow, coagulation, liver, and renal function

Young Participant Cohort

- Written informed consent obtained from parents or legal representative
- Age at enrollment: from >= 6 months to < 3 years of age
- Progressive or relapsed metastatic or localised, supra- or infratentorial, non-brain stem WHO Grade III or IV glioma (local pathology confirmation made either at initial diagnosis or at relapse)
- Availability of a baseline MRI performed according to imaging guidelines
- Adequate organ function (bone marrow, coagulation, liver, kidney)

Exclusion Criteria:

Exclusion Criteria - Main cohort:

- Metastatic HGG defined as evidence of neuraxis dissemination by MRI or positive cerebrospinal fluid (CSF) cytology
- WHO-defined Gliomatosis cerebri (multifocal HGG)
- Any disease or condition that contraindicates the use of the study medication/treatment or places the patient at an unacceptable risk of experiencing treatment-related complications
- Radiological evidence of surgically related intracranial bleeding
- Prior diagnosis of a malignancy and disease-free for 5 years
- Prior systemic anti-cancer therapy
- Previous cranial irradiation

Young Participant Cohort

- WHO-defined Gliomatosis cerebri (multifocal HGG)
- Newly diagnosed HGG below the age of 3 years
- Relapsed HGG below the age of 6 months or above the age of 3 years regardless of the age at first onset
- Indication for concomitant cranial irradiation, regardless of age
- Any disease or condition that contraindicates the use of the study medication/treatment or places the child at an unacceptable risk of experiencing treatment-related complications

- Any specific contraindication to MRI