

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
Completed

Trial Runs In
14 Countries

Trial Identifier
NCT01390948 2010-022189-28,
ITCC-019, HGG-01 BO25041

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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
Sponsor

Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
 ≥ 6 Months & ≤ 18 Years

Healthy Volunteers
No