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Temodex – A novel effective local intraoperative chemotherapy treatment for patients with neuroepithelial brain tumors

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Introduction: The efficacy of the local chemotherapeutical drug Temodex, constituted of temozolomide as active pharmaceutical ingredient and dextran phosphate as carrier, was studied in a phase II clinical trial.

Aim: The aim of the study was to assess whether Temodex improves the standard of care treatment (Stupp) for patients with operable neuroepithelial brain tumors when administered into the cavity formed after tumor resection.

Methods: The method used is an open, controlled, comparative, retro-prospective study with overall survival (OS) as primary endpoint. Totally 95 patients with Grade II-IV glioma were included in the control group and 41 in the Temodex group.

Results: Median OS of patients with highly malignant, Grade III-IV, tumors was significantly improved in the Temodex group compared to control group (14.4 vs. 9.1 months, respectively, p=0.0001). Median OS for all patients (Grade II-IV) in the Temodex group was 8.5 months longer compared to control (p=0.0001). Median PFS of patients with Grade III-IV tumors was 13.6 months in the Temodex group compared to 7.8 months in control (p=0.0001). Median PFS in patients with Grade IV tumors in the Temodex group was 12.9 months compared to 7.2 months in control (p=0,0001). One-year cumulative survival ratio of patients with Grade III-IV tumors was 51.9% higher in Temodex group compared to control (p=0.0001). At the time of the latest analysis, 74.4% patients in Temodex and 94.4% patients in the control groups had died.

Conclusion: The current study of Temodex efficacy in combination with adjuvant chemo-radiotherapy against Grade II-IV tumors demonstrates an increase in both median OS as well as in median PFS.

Biography

Iulia Karlsson has completed her PhD in Medical Biosciences from Swedish University of Agricultural Sciences and currently works as a Regulatory Affairs Specialist and Head of Companion Diagnostics and Biomarker Development at Double Bond Pharmaceutical, an innovative pharmaceutical company founded in 2014 in Sweden. She has extensive experience in clinical studies both in Human and Veterinary Medicine and a profound knowledge in Human Biology.

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