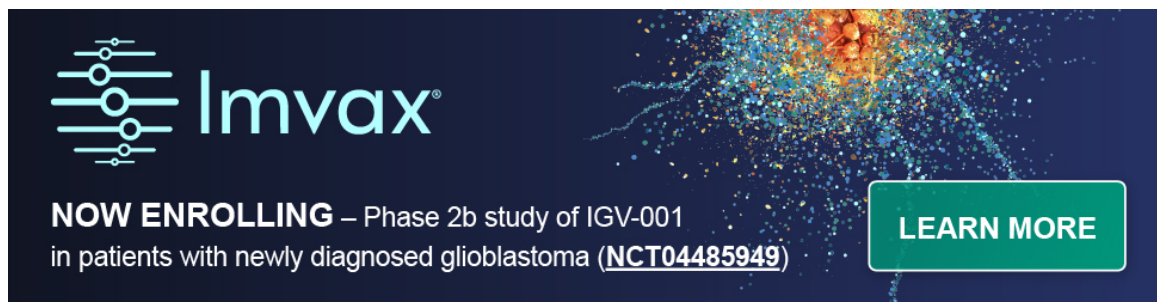


P09.03.A Associations of levetiracetam use with the safety and tolerability of chemoradiotherapy for patients with newly diagnosed glioblastoma

K Seystahl, F B Oppong, E Le Rhun, C Hertler, R Stupp, B Nabors, O Chinot, M Preusser, T Gorlia, M Weller



The banner features the Imvax logo on the left, which consists of a stylized circuit-like icon with the word "Imvax" in a teal font. To the right of the logo is a vibrant, abstract image of a galaxy or nebula with blue, orange, and yellow colors. Below the logo, the text reads "NOW ENROLLING – Phase 2b study of IGV-001 in patients with newly diagnosed glioblastoma (NCT04485949)". A green button with the text "LEARN MORE" is positioned on the right side of the banner.

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P09.03.A. ASSOCIATIONS OF LEVETIRACETAM USE WITH THE SAFETY AND TOLERABILITY OF CHEMORADIOTHERAPY FOR PATIENTS WITH NEWLY DIAGNOSED GLIOBLASTOMA

K. Seystahl¹, F. B. Oppong², E. Le Rhun^{1,3}, C. Hertler¹, R. Stupp⁴, B. Nabors⁵, O. Chinot⁶, M. Preusser⁷, T. Gorlia², M. Weller¹; ¹Department of Neurology, University Hospital and University of Zurich, Neuroscience Center, Zurich, Switzerland, ²EORTC Headquarters, Brussels, Belgium, ³Department of Neurosurgery, University Hospital and University of Zurich, Neuroscience Center, Zurich, Switzerland, ⁴Malnati Brain Tumor Institute of the Lurie Comprehensive Cancer Center and Departments of Neurosurgery and Neurology, Northwestern University Feinberg School of Medicine, Chicago, IL, United States, ⁵University of Alabama at Birmingham, Department of Neurology, Division of Neuro-Oncology, Birmingham, AL, United States, ⁶Aix-Marseille University, AP-HM, Service de Neuro-Oncologie, CHU Timone, Marseille, France, ⁷Division of Oncology, Department of Medicine 1, Medical University of Vienna, Vienna, Austria.

BACKGROUND: Levetiracetam (LEV) is one of the most frequently used antiepileptic drugs (AED) for brain tumor patients with seizures. We hypothesized that toxicity of LEV and temozolomide-based chemoradiotherapy may overlap. **PATIENTS AND METHODS:** In a retrospective analysis of individual patient data using a pooled cohort of patients with newly diagnosed glioblastoma included in clinical trials prior to chemoradiotherapy (CENTRIC, CORE, AVAglio) or prior to maintenance therapy (ACT-IV), we tested associations of hematologic toxicity, nausea or emesis, fatigue, and psychiatric adverse events during concomitant and maintenance treatment with the use of LEV alone or with other AED versus other AED alone or in combination versus no AED use at the start of chemoradiotherapy and of maintenance treatment. **RESULTS:** Of 1681 and 2020 patients who started concomitant chemoradiotherapy and maintenance temozolomide, respectively, 473 and 714 patients (28.1% and 35.3%) were treated with a LEV-containing regimen, 538 and 475 patients (32.0% and 23.5%) with other AED, and 670 and 831 patients (39.9% and 41.1%) had no AED. LEV was associated with higher risk of psychiatric adverse events during concomitant treatment in univariable and multivariable analyses (RR 1.86 and 1.88, $p < 0.001$) while there were no associations with hematologic toxicity, nausea or emesis, or fatigue. LEV was associated with reduced risk of nausea or emesis during maintenance treatment in multivariable analysis (HR=0.80, $p = 0.017$) while there were no associations with hematologic toxicity, fatigue, or psychiatric adverse events. **CONCLUSION:** Any association of psychiatric adverse events with LEV did not persist beyond the concomitant treatment phase. Antiemetic properties of LEV may be beneficial during the maintenance temozolomide.

P09.04.B. THE IMPORTANCE OF TREATMENT TOLERABILITY FOR PEOPLE WITH GLIOMA: REGISTRY REVIEW AND QUALITATIVE FINDINGS FROM THE COBRA STUDY

E. Baddeley¹, A. Retzer², S. Sivell¹, K. Seddon¹, H. Bulbeck³, A. Nelson¹, R. Adams⁴, R. Grant⁵, C. Warts⁶, O. Aiyegbusi², S. Rivera², P. Kearns⁷, L. Dirven⁸, M. Calvert², A. Byrne¹; ¹Cardiff University - Marie Curie Palliative Care Research Centre, Cardiff, United Kingdom, ²University of Birmingham - Centre for Patient Reported Outcomes Research, Birmingham, United Kingdom, ³Brainstrust, London, United Kingdom, ⁴Cardiff University - Centre for Trials Research, Cardiff, United Kingdom, ⁵University of Edinburgh, Edinburgh, United Kingdom, ⁶University of Birmingham - Institute of Cancer and Genomic Sciences, Birmingham, United Kingdom, ⁷University of Birmingham - Cancer and Genomic Sciences, Birmingham, United Kingdom, ⁸Leiden University, Leiden, Netherlands.

BACKGROUND: Gliomas are the commonest form of primary brain tumour, accounting for 80% of malignant brain tumours. Gliomas represent a heterogeneous group of cancers with variable outcomes, traditionally graded from I to IV (least to most aggressive). The poor prognosis of some glioma patients and high symptom burden has led to a growing emphasis on their quality of survival. Maintaining cognitive function, physical function and other health-related quality of life aspects throughout the disease trajectory are key considerations, particularly for patients with aggressive forms of glioma. It is therefore important that glioma intervention studies collect data aligned with patient priorities that enables assessment of the net clinical benefit of treatments and facilitates informed decision-making. In particular, and of increasing recognition, is the importance of monitoring the incidence of adverse events during and after the course of an intervention, and understanding their impact upon patients, and patients' own assessment of, tolerability. **MATERIAL AND METHODS:** A trial registry review, a systematic review of the qualitative literature and semi-structured interviews with patients and caregivers were undertaken. Outcomes were extracted from these sources to formulate a longlist during the development of a core outcome set for glioma interventional trials (the COBRA study). **RESULTS:** The registry review ($n=91$), systematic review ($n=21$) and semi-structured interviews ($n=19$) identified many important outcomes and concepts, one of which was

tolerability. Tolerability, adverse events, toxicity or safety was reported to be collected as an outcome in 46 trials. Outcomes related to tolerability were identified from 7 articles included in the systematic review. Themes related to tolerability emerged from the qualitative interviews. These included tolerability of side effects of treatment; trade-offs of side effects versus potential benefits in deciding on, and willingness to, undertake further treatment; and self-directed strategies for coping. **CONCLUSION:** There is a growing acknowledgement of the importance of treatment tolerability in the wider field of cancer research. In glioma research specifically, its significance is yet to be reflected in outcomes collected in trials. Our qualitative findings indicate tolerability is of high significance to patients and those close to them. Participants reported how their preconceptions and experience of tolerability influenced treatment decisions and treatment uptake. However, outcomes related to tolerability were collected in just over half of trials in our sample. Tolerability and items relating to the patients' experience of adverse events should be collected and reported in trial findings to reflect patients' priorities and enable informed treatment decisions.

P09.05.A. CAREGIVER CAFÉ IN A NEURO-ONCOLOGICAL CONTEXT

M. Mathiasen, C. Bang Rasmussen, K. Pii; The University Hospital of Copenhagen, Rigshospitalet, København ø, Denmark.

BACKGROUND: Caregivers to patients with primary brain tumors often play a vital role in the direct care and support of the patient. Great responsibility is placed on their shoulders to manage practicalities during the cancer trajectory. Caregivers are asked to carry out procedures, report patient-related evaluations, coordinate care and treatment and deliver proper information to the healthcare providers. Hence, they tend to neglect their own physical and emotional needs as they prioritize other tasks including financial issues, household and work while coping with family adjustment. Caregivers of patients with brain tumors experience a high level of burden and distress. It is shown in literature that caregiver interventions can reduce caregiver burden, distress and anxiety, and improve coping, relationships and physical functioning.

Aim: The aim of this study is to offer caregivers to join a caregiver café at the neuro-oncological department to 1) relax, meet and support each other, (2) be provided with information and answers to their questions, and (3) be recommended appropriate caregiver services. **MATERIAL AND METHODS:** This is a user-based sequential three phase project. Applying a co-creation process with informal caregivers we first investigate their preferences, needs and considerations in relation to establishing a caregiver café. A user survey consisting of demographic characteristics and five study-specific and open-ended questions are conducted. Secondly, a project protocol with the design, content and practical planning will be outlined and presented for the patient/relative-user panel at the oncological department. After the final adjustment, a feasibility testing will take place in phase three. **RESULTS:** This three-phase project rest on a sequential project development, and findings from one phase will lead to the detailed adjustment in the next. Due to its nature of following a participatory design we consider the results to be highly relevant to the users of health-care services. Results from phase I and II is ready to be presented in autumn 2022 including the preliminary results of the feasibility study (recruitment, adherence, safety etc). **CONCLUSION:** Nurses working within neuro-oncology are e.g responsible for providing support, information and education for family caregivers. This project may inspire other nurses to carry out similar initiatives in clinical practice. Thereby we seek to strengthen the evidence on how, what and when the caregivers' needs and concerns are best addressed with innovative solutions. **ACKNOWLEDGEMENT:** We like to thank the nurses at the neuro-oncology department, Rigshospitalet for their valuable input and for their participating with the user survey.

P09.06.B. THE EFFECTIVENESS OF ANTIPILEPTIC DRUG TRIPLE THERAPY IN REFRACTORY EPILEPTIC GLIOMA PATIENTS: A MULTICENTER OBSERVATIONAL COHORT STUDY

P. B. van der Meer¹, L. Dirven¹, M. Fiocco¹, M. J. Vos², M. C. M. Kouwenhoven³, M. J. van den Bent⁴, M. J. B. Taphoorn¹, J. A. F. Koekkoek¹; ¹Leiden University Medical Center, Leiden, Netherlands, ²Haaglanden Medical Center, The Hague, Netherlands, ³Amsterdam University Medical Center, Amsterdam, Netherlands, ⁴Erasmus Medical Center, Rotterdam, Netherlands.

BACKGROUND: About 10% of the glioma patients need antiepileptic drug (AED) tripletherapy due to refractory epilepsy. This study aimed to determine whether levetiracetam combined with valproic acid and clobazam (LEV+VPA+CLB), a commonly prescribed tripletherapy, has favourable effectiveness compared to other tripletherapy combinations in glioma patients. **MATERIAL AND METHODS:** In this multicenter retrospective observational cohort study, the primary outcome was the cumulative incidence of treatment failure for any reason, from initiation of AED tripletherapy. Secondary outcomes included cumulative incidences of: 1) treatment failure due to uncontrolled