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A double-blind controlled clinical trial of oxcarbazepine versus phenytoin in adults with previously untreated epilepsy.

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Abstract

In the last 5 years oxcarbazepine (OXC) has been registered in many countries for use as first-line and add-on treatment for partial seizures with or without secondarily generalized seizures (PS) and generalized tonic-clonic seizures without partial onset (GTCS). Its use as monotherapy in adults with newly diagnosed epilepsy was investigated in this double-blind, randomized, parallel-group comparison with phenytoin (PHT). A total of 287 adult patients, with either PS or GTCS, were randomized. After retrospective baseline assessment, patients were randomized to OXC or PHT in a 1:1 ratio. The double-blind treatment phase was divided into two periods: a flexible titration period of 8 weeks, followed by 48 weeks of maintenance treatment. In the efficacy analyses, no statistically significant differences were found between the treatment groups. Seventy patients (59.3%) in the OXC group and 69 (58.0%) in the PHT group were seizure-free during the maintenance period. A total of 56 of the patients in the OXC group discontinued treatment prematurely (five because of tolerability reasons) compared to 61 in the PHT group (16 for tolerability reasons). The number of premature discontinuations due to adverse experiences showed a statistically significant difference in favour of OXC. There was no statistically significant difference between the groups with respect to the total number of premature discontinuations. This trial provides further support for the efficacy and safety of OXC as first-line treatment in adults with PS and GTCS. In addition, the results show that OXC has significant advantages over PHT in terms of tolerability.

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