

## A Placebo-Controlled Randomized Trial of Vigabatrin in the Management of Alcohol Withdrawal Syndrome

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**Introduction:** Alcohol withdrawal management is a critical element of care for people with alcohol use disorders (AUD). Currently, pharmacological management involves administration of varying dosages of benzodiazepines calibrated to each individual which can be complex to deliver. We performed a double blinded randomised placebo-controlled trial to assess the efficacy of vigabatrin, a GABA-transaminase inhibitor, in the management of acute alcohol withdrawal syndrome.

**Method:** We enrolled 120 patients with AUD who were randomly assigned to either treatment with vigabatrin (2g/day for 4 days) or placebo. The primary outcome was defined as the number of participants in each treatment arm needing diazepam for withdrawal management. A secondary outcome was the total dose of diazepam received by participants in each treatment arm. Participants were recruited on admission to a residential withdrawal unit from December 2014 to April 2019.

**Results:** No difference was observed in the number of participants requiring any benzodiazepines during their residential withdrawal stay, 44 participants (78.6%) in placebo arm compared to 38 (66.7%) in vigabatrin arm ( $p = .156$ ). An 18.1% difference was observed between the proportion of participants who received a total dose of >100mg of diazepam in placebo arm (32.1%), compared to vigabatrin arm (14.0%,  $p = .022$ ). There were higher rates of reported adverse events in placebo arm with nine (15.0%) vs two (3.3%) in vigabatrin arm ( $p = .027$ ).

**Conclusions:** Vigabatrin significantly reduced the number of participants requiring >100mg diazepam over the course of their alcohol withdrawal and was associated with a reduction in adverse effects when compared to placebo

**Implications for Practice or Policy:** Vigabatrin could be incorporated into alcohol withdrawal management protocols, particularly for individuals who require high doses of benzodiazepines. Further research to confirm these findings and explore a range of common alcohol related co-morbidities should be performed.

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