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LONG-TERM EFFICACY OF NALMEFENE AS-NEEDED IN ALCOHOL DEPENDENT PATIENTS WITH HIGH DRINKING RISK LEVELS: RESULTS OF A SUBGROUP ANALYSIS

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Introduction: We describe the efficacy and safety of as-needed use of nalmefene in the subgroup of patients with a high drinking risk level (DRL; men:>60g/day; women:>40g/day); i.e. a group of patients with a great unmet medical need for treatment.
Objectives: To evaluate the 1 year efficacy and safety of as-needed use of nalmefene 18mg *versus* placebo in a subgroup of alcohol dependent patients with high DRL from a randomised controlled trial [NCT00811941].
Methods: All patients received a motivational and adherence-enhancing intervention (BRENDA) in combination with either nalmefene or placebo. Number of heavy drinking days (HDDs) and total alcohol consumption (TAC) were measured using the Timeline Follow-back method. Additionally, data on clinical improvement, liver function and safety were collected throughout the study.
Results: The study population consisted of 187 patients: placebo N=42; nalmefene N=145 (mean age 46.2±11.9 years; 78% men; mean HDDs 19±6.3/month; mean TAC 101±45.0 g/day). Mean number of HDDs decreased to 7 days/month and mean TAC decreased to 33g/day at 1 year in the nalmefene group. At 1 year, there was a superior effect of nalmefene compared to placebo in reducing the number of HDDs (-3.6 [95% CI:-6.5;-0.7]; p=0.0164) and TAC -17.3 [-30.9;-3.8]; p=0.0129). Improvements in clinical status and in liver enzymes from baseline were larger in the nalmefene compared to the placebo group. Adverse events and adverse events leading to dropout were more common with nalmefene than placebo.
Conclusions: As-needed nalmefene was efficacious in reducing alcohol consumption in patients with high risk for alcohol-related harm.