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# ESENSE 1 - RANDOMISED CONTROLLED 6-MONTH STUDY OF AS-NEEDED NALMEFENE: SUBGROUP ANALYSIS OF ALCOHOL DEPENDENT PATIENTS WITH HIGH DRINKING RISK LEVEL

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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 6 month 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 [NCT00811720].
**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 350 patients: placebo N=170; nalmefene N=180 (mean age 51.9±9.4 years; 63% men; mean HDDs: 23±5.7/month; mean TAC: 101±41.7g/day). Mean number of HDDs decreased to 11 days/month and mean TAC decreased to 44g/day at month 6 in the nalmefene group. There was a superior effect of nalmefene compared to placebo in reducing the number of HDDs (-3.7 [95% CI: -5.9;-1.5];p=0.0010) and TAC (-18.3 [-26.9;-9.7];p< 0.0001) at month 6. Improvements in clinical status and liver parameters were greater in the nalmefene group compared to the placebo group (p< 0.05). 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.

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