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ESENSE 2 - RANDOMISED CONTROLLED 6-MONTH STUDY OF AS-NEEDED NALMEFENE: SUBGROUP ANALYSIS OF ALCOHOL DEPENDENT PATIENTS WITH HIGH DRINKING RISK LEVEL

W. van den Brink[1]*, H.-J. Aubin*[2]*, P. Sørensen*[3]*, L. Torup*[3]*, K. Mann*[4]*, A. Gual*[5]

[1]Department of Psychiatry, Amsterdam Institute for Addiction Research, University of Amsterdam, Amsterdam, The Netherlands, [2]Hôpital Paul Brousse, INSERM 669, Université Paris-Sud,, Villejuif, France, [3]H. Lundbeck A/S, Valby, Denmark, [4]Department of Addictive Behaviour and Addiction Medicine, Central Institute of Mental Health, University of Heidelberg, Mannheim, Germany, [5]Department of Psychiatry, Alcohol Unit, Institute of Neurosciences, Hospital Clinic, Barcelona, Spain

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.
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 [NCT00812461].
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 317 patients: placebo N=162; nalmefene N=155 (mean age 44.8±10.3 years; 69% men; mean HDDs: 22±6.2/month; mean TAC 111±47.9g/day). Mean number of HDDs decreased to 10 days/month and mean TAC decreased to 43g/day at month 6 in the nalmefene group. There was a superior effect of nalmefene compared to placebo in reducing the number of HDDs (-2.7 [95% CI: -5.0;-0.3];p=0.0253) and TAC -10.3 [-20.2;-0.5];p=0.0404). Improvements in clinical status and alanine amino transferase were greater in the nalmefene group compared to the placebo group ($p< 0.05$). Adverse events were more common with nalmefene; incidence of adverse events leading to dropout was at the placebo level.
Conclusions: As-needed nalmefene was efficacious in reducing alcohol consumption in patients with high risk for alcohol-related harm.