HIGH DOSE BACLOFEN FOR THE TREATMENT OF ALCOHOL DRINKERS (BACLOVILLE) ClinicalTrials.gov Identifier: NCT01604330.

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Bacloville is a pragmatic therapeutic trial randomized, double-blind for a year in ambulatory care of high dose of baclofen versus placebo. (Phase 2b).
The main objective of this study was to show the effectiveness to a year of baclofen compared to placebo, on the proportion of patients with a low risk alcohol consumption or no consumption, according to the WHO standards.
Main inclusion criteria were:
Patient (from 18 years to 65 years old) coming for a problem with alcohol (alcohol at high risk during the past three months (at least two times during each month) according to the WHO standards and expressing the desire to be abstinent or to have consumption to low level of risk).
Volunteer to participate in the trial and having given his consent written after appropriate information.
Patient having no treatment for the maintenance of abstinence (acamprosate, naltrexone) and the prevention of relapse (disulfiram) for at least 15 days before the beginning of the trial.
Main exclusion criteria were:
Patient taking already baclofen or having taken baclofen.
Patient pregnant, lactating, or childbearing years in the absence of effective contraception.
Patient with severe psychiatric pathology (psychosis, including schizophrenia and bipolar disorders) that could compromise the observance.
Patient with organic disease serious enough to not to allow its inclusion in the study according to the opinion of the investigator.
Patient patient homeless.

Patient without social cover.
Patient unable to properly follow-up book, cannot commit to one year of follow-up.
The drug was administered orally for a maximum of 52 consecutive weeks.
For the first 3 days, patients received the drug in a dose of 5 milligrams three times a day; then the dose was increased to a maximum of 300 milligrams a day.
In case of intolerance, dosage could be decreased.
The study began in May, 2012 and the last participant (321) was included in June, 2013.
The primary completion date was September 2014 (final data collection date for primary outcome measure) and the study completion date October 2015.

Results will be presented at this session.

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