Baclofen for the Treatment of Alcohol Drinkers (BACLOVILLE)

This study has been completed.

Sponsor:
Assistance Publique - Hôpitaux de Paris

Collaborators:
Société de Formation Thérapeutique du Généraliste
Cochin Hospital, Paris, Professor Claire Le Jeunne - Chief Scientist

Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

ClinicalTrials.gov Identifier:
NCT01604330

First received: May 21, 2012
Last updated: December 21, 2015
Last verified: October 2015
History of Changes

Purpose

The main objective of this study is 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, according to the WHO standards.

Condition	Intervention	Phase
Alcoholism	Drug: Baclofen Drug: Placebo	Phase 2 Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Alcohol Treatment: Pragmatic Therapeutic Trial Randomized, Double-blind for a Year in Ambulatory Care of Baclofen Versus Placebo.

Resource links provided by NLM:

MedlinePlus related topics: Alcoholism and Alcohol Abuse

Drug Information available for: Baclofen

U.S. FDA Resources

Further study details as provided by Assistance Publique - Hôpitaux de Paris:

Primary Outcome Measures:

- Proportion of abstainer patients and patients with a low risk consumption [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: Yes]

  Low risk consumption according to the criteria of WHO (World Health Organization). The assessment will be on the declarative of the patient (with autoquestionnaire). It will be compared between the two groups using a Chi-2 test.

Secondary Outcome Measures:

- Distribution of Efficience dosage of baclofen [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: Yes]

  Published studies indicate that the average dose would be about 140 mg per day without, a priori, report with the weight of the patient. Animal studies show an optimal dose of 3 mg/kg.

- To evaluate the tolerance of baclofen [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: Yes]

  To try, if possible, to differentiate which is due to the molecule, which is due to the stop of drinking alcohol and which is due to the alcohol-

baclofen potentiation and looking for all the side effects including at high dosages.

- To better characterize the alcoholic patients in whom this molecule is effective [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: No]

  By using the anxiety/depression HAD scale. By using the scale of craving (Obsessive Compulsive Drinking Scale). By using the DSM - IV for the dependency.

- Evolution of patients under treatment [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: No]

  At each consultation, the consumption self-assessment questionnaire is analysed with the patient (book of follow-up) and missing data are sought and completed. To describe the evolution of patients under treatment from the point of view of the total consumption of alcohol, the monthly average consumption, the number of days of abstinence, the number of "heavy drinking days".

- Cumulative quantity of alcohol drunk in the last month [Time Frame: 12 months after the initiation of treatment] [Designated as safety issue: No]

  To analyse the cumulative quantity of alcohol drunk by the patient during the last month of treatment

- Quality of life during treatment [Time Frame: at Day 1 and 12 months after the initiation of treatment] [Designated as safety issue: No]

  To assess the quality of life during treatment by using the scale SF36 at the beginning and at the end of the study.

- Evolution of biology [Time Frame: At day one, 6 months and 12 months after the initiation of treatment] [Designated as safety issue: No]

  To study the evolution of biology, including liver, compared to the declaration made by the patient from his response to treatment. Biological examinations will be performed at the beginning, at 6 month and at the end of the trial.

Enrollment:	323
Study Start Date:	May 2012
Study Completion Date:	October 2015
Primary Completion Date:	September 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Baclofen Baclofen will be administered orally for a maximum of 52 consecutive weeks. For the first 3 days, patients will receive baclofen in a dose of 5 milligrams three times a day; then the dose of baclofen will be increased to a maximum of 300 milligrams a day. In case of intolerance, dosage can be decreased.	Drug: Baclofen Baclofen will be administered orally for a maximum of 52 consecutive weeks. For the first 3 days, patients will receive baclofen in a dose of 5 milligrams three times a day; then the dose of baclofen will be increased to a maximum of 300 milligrams a day. In case of intolerance, dosage can be decreased.
Placebo Comparator: Placebo Sugar pill will be administered orally for a maximum of 52 consecutive weeks. For the first 3 days, patients will receive sugar pill in a dose of 5 milligrams three times a day; then the dose of sugar pill will be increased to a maximum of 300 milligrams a day. In case of intolerance, dosage can be decreased.	Drug: Placebo Sugar pill will be administered orally for a maximum of 52 consecutive weeks. For the first 3 days, patients will receive sugar pill in a dose of 5 milligrams three times a day; then the dose of sugar pill will be increased to a maximum of 300 milligrams a day. In case of intolerance, dosage can be decreased.

Detailed Description:
Baclofen, a gamma-aminobutyric acid 'B-receptor' agonist, has long been used to treat spasticity from neurological diseases, at a dose of 30-90 mg/day. It appears today to be a promising but controversial candidate for treating alcoholic patients (Enserick, 2011) by reducing or even suppressing their craving to drink. A few case reports (Ameisen, 2005; Bucknam, 2007; Dore et al., 2011) and a retrospective study (Rigal et al, 2012) suggest that some patients might respond favorably to baclofen at higher doses than 90 mg/day. This is a randomized controlled trial versus placebo testing such doses.

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient 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;. i.e.: in women more than 40 g per day or 280 g per week or more of 40 g at once; the man more than 60 g per day or 420 g per week or more than 60 g in once, and expressing the desire to be abstinent or to have a 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

- Patient informed about the possibility of drowsiness in relation to the treatment and the associated risks to drive vehicles (motorized or not), the use of machines (including domestic use or recreation) and the execution of tasks requiring attention and precision
- Including woman of childbearing age (but taking effective contraception).

Exclusion Criteria:

- Patient taking already baclofen or having taken baclofen
- Patient pregnant, lactating, or childbearing years in the absence of effective contraception
- Patient with porphyria
- Patient with Parkinson's disease
- Patient with severe psychiatric pathology (psychosis, including schizophrenia and bipolar disorders) that can 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 homeless
- Patient without social cover
- Patient unable to properly follow-up book, cannot commit to one year of follow-up
- Patient with a contraindication to taking baclofen (intolerance to gluten by the presence of wheat starch
- Patient with a severe intolerance known about the lactose

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01604330

Locations

France

Paris Descartes University
Paris, France, 75014

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Société de Formation Thérapeutique du Généraliste

Cochin Hospital, Paris, Professor Claire Le Jeunne - Chief Scientist

Investigators

Principal Investigator: Philippe Jaury, MD, PhD Paris Descartes University

More Information

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ClinicalTrials.gov Identifier:	NCT01604330 History of Changes
Other Study ID Numbers:	P110112 2011-005787-17
Study First Received:	May 21, 2012
Last Updated:	December 21, 2015
Health Authority:	France: Ministry of Health

Keywords provided by Assistance Publique - Hôpitaux de Paris:
High dose baclofen
Alcoholism
Abstinence
Low risk consumption
Craving

Additional relevant MeSH terms:
Alcoholism
Alcohol-Related Disorders
Chemically-Induced Disorders
Mental Disorders
Substance-Related Disorders

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