Efficacy and Safety of Baclofen for Maintenance of Abstinence in Alcohol Dependent Patients (ALPADIR)

Purpose

The purpose of the study is to assess the efficacy of Xylka® (baclofen) compared to placebo on continuous abstinence rate during 20 weeks of treatment, after withdrawal, in alcohol dependent patients receiving Brenda therapy sessions.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Dependence</td>
<td>Drug: Baclofen</td>
<td>Phase 3</td>
</tr>
<tr>
<td></td>
<td>Drug: Placebo (for baclofen)</td>
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</tr>
</tbody>
</table>

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

Official Title: A Randomized, Multicentric, Double Blind Study to Assess the Efficacy of Xylka® (Baclofen) at the Target Dosage of 180mg/Day Compared to Placebo, for Maintenance of Abstinence in Alcohol Dependent Patients

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 Ethypharm:

Primary Outcome Measures:
- Continuous abstinence rate in each group (baclofen or placebo) during 20 weeks of treatment, from Day 29 to Day 168. [ Time Frame: Day 168 ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Continuous abstinence rate from the first intake of study treatment (Day 1) to the end of the maintenance dose period (Day 168), i.e. 24 weeks [ Time Frame: Day 168 ] [ Designated as safety issue: No ]
- Continuous abstinence rate from the first intake of study treatment (Day 1) to the end of 4-week post treatment follow up period (Day 210), i.e. 30 weeks [ Time Frame: Day 210 ] [ Designated as safety issue: No ]
- Continuous abstinence rate during 20 weeks of treatment (Day 29 to Day 168), according to the severity of alcohol dependence [ Time Frame: Day 168 ] [ Designated as safety issue: No ]
- Continuous abstinence rate during 20 weeks of treatment (Day 29 to Day 168), according to the level of drinking before withdrawal (Time Line Follow Back calendar/ World Health Organization criteria for risk of consumption) [ Time Frame: Day 168 ] [ Designated as safety issue: No ]
- Drinking characteristics for patients having a relapse between Day 1 and Day 210 [ Time Frame: Day 210 ] [ Designated as safety issue: No ]
- Time to relapse (Day 1 to first drinking day) Time to relapse to first high risk drinking day (>60g for a male, > 40g for a female) Percentage of drinking days from Day 1 to Day 210 Mean number of standard drinks per drinking day and classification according to World Health Organization criteria for the risk of consumption Percentage of high risk drinking days during the maintenance period at the target dosage (Day
Percentage of drinking days during the maintenance period at the target dosage (Day 50 to Day 168) compared to the percentage of drinking days during the preceding 4 weeks of the withdrawal.

- Change in craving, addiction and Quality of Life scales [Time Frame: Day 210] [Designated as safety issue: No]
  - Clinical Global Impression (CGI), Alcohol dependence Quality of Life (AlQoL9), Obsessive Compulsive Drinking Scale (OCDS), Hospital Anxiety and Depression Scale (HAD), Visual Analogue Scale (VAS) craving scores and liver biomarkers

- Recording of safety data [Time Frame: Day 210] [Designated as safety issue: Yes]
  - Adverse events, vital signs, biological parameters, ECG and urinary pregnancy test

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**Estimated Enrollment:** 316
**Study Start Date:** December 2012
**Study Completion Date:** July 2014
**Primary Completion Date:** July 2014 (Final data collection date for primary outcome measure)

**Arms**

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experimental: Baclofen</strong></td>
<td>Drug: Baclofen</td>
</tr>
<tr>
<td>Baclofen 20mg tablet. Titration: increasing dosage regimen to reach the target dosage of 180 mg (9 tablets) in 7 weeks Maintenance period with a constant dosage during 17 weeks Progressive decrease and stop of study treatment in 2 weeks</td>
<td></td>
</tr>
<tr>
<td><strong>Placebo Comparator: Placebo</strong></td>
<td>Drug: Placebo (for baclofen)</td>
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**Eligibility**

**Ages Eligible for Study:** 18 Years and older
**Genders Eligible for Study:** Both
**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- Adult patients meeting DSM IV (Diagnosis and Statistical Manual of Mental Disorders, 4th edition) criteria for alcohol dependence
- Willing to participate in the study and express a desire to achieve the objective of continuous and long term abstinence after withdrawal
- Abstinent (last drinking) for a minimum of 3 days and maximum of 14 days
- At least one previous abstinence attempt

**Exclusion Criteria:**
- Need for a stay at the end of the withdrawal period in a health care and rehabilitation institution specialized in addiction
- Need for a heavy psychosocial out of hospital care
- History of baclofen intake, by prescription or self medication
- Porphyria
- Concomitant treatment with one or several drugs for the maintenance of abstinence
- Severe renal, cardiac or pulmonary disorder
- Epilepsy or history of epilepsy
- Concomitant treatment with psychotropic drugs, except antidepressants at stable dose for 2 months, diazepam and oxazepam
- Severe psychiatric disease (schizophrenia and bipolar disorder)
- Suicidal risk or history of suicide
- Clinically significant cognitive disorders
- Hepatic encephalopathy
- Ongoing dependence or within the last 12 months on other addictive substances (opioid, cocaine, cannabis, other substances or drugs…), excepted tobacco

**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.
Locations

France

Angers, France
Bron, France
Clermont de l'Oise, France

CHU
Clermont Ferrand, France

Hopital Beaujon
Clichy, France
Dax, France

Centre hospitalier
Dijon, France

Centre hospitalier
Erstein, France
L'Arbresle, France

Centre hospitalier
La Membrolle sur Choisille, France

Hopital Michallon
La Tronche, France

Centre hospitalier
Le Mans, France

CHRU
Lille, France

CSAPA
Lille, France
Limoges, France

Hopital de la Croix Rousse
Lyon, France

Hopital Sainte Marguerite
Marseille, France

Centre hospitalier
Montauban, France
Morlaix, France

Hopital Villemin
Nancy, France

CHU
Nantes, France

Centre hospitalier
Nice, France

CHRU
Nimes, France

Hopital Bichat Claude Bernard
Paris, France

Hopital Cochin
Paris, France

Hopital Fernand Widal
Paris, France

Hopital Saint Anne
Paris, France

Centre hospitalier
Perpignan, France

Centre hospitalier
Pont du Casse, France
Reims, France

Hopital Pontchaillou
Rennes, France

Hopital de la Fraternité
Sponsors and Collaborators

Ethypharm

Investigators

Principal Investigator: Michel REYNAUD, MD Villejuif, France

More Information

Responsible Party: Ethypharm
ClinicalTrials.gov Identifier: NCT01738282 History of Changes
Other Study ID Numbers: ALP 2011007/002
Study First Received: November 26, 2012
Last Updated: July 29, 2014
Health Authority: France: Agence Nationale de Sécurité du Médicament et des produits de santé

Keywords provided by Ethypharm:
- baclofene
- Alcohol dependence
- Maintenance of abstinence

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

ClinicalTrials.gov processed this record on May 05, 2016