Clinical trials

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn more about the EU Clinical Trials Register including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays 27886 clinical trials with a EudraCT protocol, of which 4175 are clinical trials conducted with subjects less than 18 years old. The register also displays information on 18612 older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

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<thead>
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<th>Summary</th>
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<tr>
<td>EudraCT Number:</td>
<td>2011-004142-17</td>
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<tr>
<td>Sponsor's Protocol Code Number:</td>
<td>17082011</td>
</tr>
<tr>
<td>National Competent Authority:</td>
<td>Netherlands - Competent Authority</td>
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<td>Clinical Trial Type:</td>
<td>EEA CTA</td>
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<td>Trial Status:</td>
<td>Ongoing</td>
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<td>Date on which this record was first entered in the EudraCT database:</td>
<td>2012-02-24</td>
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Trial results

### Protocol Information

| A.1 | Member State Concerned: | Netherlands - Competent Authority |
| A.2 | EudraCT number: | 2011-004142-17 |
| A.3 | Full title of the trial: | High-dose baclofen for the treatment of alcohol addiction - A double-blind, randomized, placebo-controlled study |
| A.3.1 | Title of the trial for lay people, in easily understood, i.e. non-technical, language: | High-dose baclofen for the treatment of alcohol addiction |
| A.4.1 | Sponsor's protocol code number: | 17082011 |
| A.7 | Trial is part of a Paediatric Investigation Plan: | No |
| A.8 | EMA Decision number of Paediatric Investigation Plan: |  |

### Sponsor Information

| B.1 | Name of Sponsor: | Academic Medical Centrum |
| B.1.3.4 | Country: | Netherlands |
| B.3.1 | Status of the sponsor: | Non-Commercial |
| B.4 | Name of organisation providing support: | Amsterdams Fonds voor Verslavingsonderzoek |
| B.4.2 | Country: | Netherlands |
| B.5 | Name of organisation: | University of Amsterdam |
| B.5.2 | Functional name of contact point: | Clinical Trials Information Baclofe |
| B.5.3 | Address: |  |
| B.5.3.1 | Street Address: | Weesperplein 4 |
| B.5.3.2 | Town/ city: | Amsterdam |
**1. IMP Identification**

**D. IMP: 1**

**D.1.2 and D.1.3**
**IMP Role**
Test

**D.2**
**Status of the IMP to be used in the clinical trial**

**D.2.1**
**IMP to be used in the trial has a marketing authorisation**
Yes

**D.2.1.1**
**Trade name**
Baclofen

**D.2.1.2**
**Name of the Marketing Authorisation holder**
ratiopharm nederland BV

**D.2.1.3**
**Country which granted the Marketing Authorisation**
Netherlands

**D.2.5**
**The IMP has been designated in this indication as an orphan drug in the Community**
No

**D.2.5.1**
**Orphan drug designation number**

**D.3 Description of the IMP**

**D.3.1**
**Product name**
Baclofen

**D.3.2**
**Product code**
RVG 21993=12153

**D.3.4**
**Pharmaceutical form**
Tablet

**D.3.4.1**
**Specific paediatric formulation**
No

**D.3.7**
**Routes of administration for this IMP**
Oral use

**D.3.8 to D.3.10 IMP Identification Details (Active Substances)**

**D.3.8**
**INN - Proposed INN**
BACLOFEN

**D.3.9.1**
**CAS number**
1134-47-0

**D.3.9.3**
**Other descriptive name**
Lioresal

**D.3.10**
**EV Substance Code**
SUB05667MIG

**D.3.10.1**
**Concentration unit**
mg milligram(s)

**D.3.10.2**
**Concentration type**
range

**D.3.10.3**
**Concentration number**
30 to 150

**D.3.11 The IMP contains an:**

**D.3.11.1**
**Active substance of chemical origin**
Yes

**D.3.11.2**
**Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP)**
No

**The IMP is a:**

**D.3.11.3**
**Advanced Therapy IMP (ATIMP)**
No

**D.3.11.3.1**
**Somatic cell therapy medicinal product**
No

**D.3.11.3.2**
**Gene therapy medical product**
No

**D.3.11.3.3**
**Tissue Engineered Product**
No

**D.3.11.3.4**
**Combination ATIMP (i.e. one involving a medical device)**
No

**D.3.11.3.5**
**Committee on Advanced therapies (CAT) has issued a classification for this product**
No

**D.3.11.4**
**Combination product that includes a device, but does not involve an Advanced Therapy**
No

**D.3.11.5**
**Radiopharmaceutical medicinal product**
No

**D.3.11.6**
**Immunological medicinal product (such as vaccine, allergen, immune serum)**
No

**D.3.11.7**
**Plasma derived medicinal product**
No

**D.3.11.8**
**Extractive medicinal product**
No

**D.3.11.9**
**Recombinant medicinal product**
No

**D.3.11.10**
**Medicinal product containing genetically modified organisms**
No

**D.3.11.11**
**Herbal medicinal product**
No

**D.3.11.12**
**Homeopathic medicinal product**
No

**D.3.11.13**
**Another type of medicinal product**
No

**2. Information on Placebo**

**D.8 Placebo: 1**

**D.8.1**
**Is a Placebo used in this Trial?**
Yes

**D.8.3**
**Pharmaceutical form of the placebo**
Tablet

**D.8.4**
**Route of administration of the placebo**
Oral use

**3. General Information on the Trial**

**E.1 Medical condition or disease under investigation**

**E.1.1**
**Medical condition(s) being investigated**
Alcohol dependence

**E.1.1.1**
**Medical condition in easily understood language**
Alcohol addiction

**E.1.1.2**
**Therapeutic area**
Psychiatry and Psychology [F] - Behaviours [F01]

**MedDRA Classification**

**E.1.3**
**Condition being studied is a rare disease**
No

**E.2 Objective of the trial**
Main objective of the trial

The primary goal of the present study is to examine the efficacy of high dose baclofen for the treatment of patients with AD in a double-blind, randomized, placebo controlled study.

Secondary objectives of the trial

Furthermore, as a secondary study objective, factors, which may predict the treatment response of baclofen are investigated. In order to assess which patients benefit the most of the treatment with baclofen, it is proposed to examine the role of:
- anxiety
- motives to drink
- personality
- family history and age of onset of AD
- genetic endowments

Trial contains a sub-study

No

Principal inclusion criteria

- Male and Female patients, aged between 18-60 years
- Participants have a current DSM-IV diagnosis of alcohol dependence
- Participants sign a witnessed informed consent
- Participants have a breath alcohol concentration lower than 0.05 at the screening visit
- Participants must have been drinking ≥ 14 drinks (female) or ≥ 21 drinks (males) on average per week over a consecutive 30-day period in the 90-day period prior to the start of the study and have two or more days of heavy drinking (5 drinks for females, 6 drinks for males) in the 90-day period prior to the start of the study
- Participants must have had a minimum of 96 hours of abstinence prior to the start of the study
- Participants can be abstinent for a maximum of 21 days prior to the start of the study
- Participants must be able to speak and understand dutch
- Participants provide an identified locator person that can be contacted during the study in the event of loss of contact

Principal exclusion criteria

- Participants with severe psychiatric disorders (schizophrenia, schizoaffective disorder, bulimia/anorexia, dementia, or ADHD requiring medication) except for depression, bipolar disorder and anxiety
- Participants with serious medical illnesses (Parkinson's disease, gastric ulcer, duodenal ulcer, cerebrovascular disease, respiratory insufficiency, hepatic or renal insufficiency, and epilepsy)
- Participants who are at risk of suicide evaluated by the suicidality module of M.I.N.I.
- Participants who have a cognitive impairment which is likely to interfere with the understanding of the study and its procedures
- Participants with a diagnosis of dependence on any drugs except for nicotine, cannabis, alcohol and caffeine, if alcohol dependence doesn't represent the main addiction
- Participants who are or could be pregnant or nursing infants
- Participants who intend to engage in additional treatment for alcohol-related problems (except for self-help treatments which are not considered as formal treatment)
- Participants with current or recent (3 month prior to the start of the study) treatment with anti-craving medication (acamprosate, naltrexone, disulfiram, or topiramate)
- Participants who have had more than seven days of inpatient treatment for substance use disorder in the 30 days prior to the start of the study
- Participants who have used baclofen in the last 30 days

Primary end point(s)

Based on earlier literature it is expected that 70 % of patients treated with baclofen will achieve and maintain abstinence throughout the experimental period, compared to 20 % of the patients in the placebo condition.

Timepoint(s) of evaluation of this end point

after 18 weeks

Secondary end point(s)

It is expected that there will be a decrease of anxiety, caused by baclofen. Furthermore, a greater number of participants with coping motives will maintain abstinence compared to patients with enhancement motives. Furthermore, it is expected that particular genes predict treatment response.

Timepoint(s) of evaluation of this end point

after 18 weeks

Scope of the trial

Diagnosis
No
Prophylaxis
No
Therapy
Yes
Safety
Yes
Efficacy
Yes
Pharmacokinetic
No
Pharmacodynamic
No
Bioequivalence
No
Dose response
No
Pharmacogenetic
Yes
Pharmacogenomic
No
Pharmacoeconomic
No
Others
No

Trial type and phase

Human pharmacology (Phase I)
No
First administration to humans
No
Bioequivalence study
No
Other
No
Other trial type description

Therapeutic exploratory (Phase II)
No
Therapeutic confirmatory (Phase III)
Yes
Therapeutic use (Phase IV)
Yes

Design of the trial

Controlled
Yes
Randomised
Yes
### E.8.1 Clinical Trial Design

| E.8.1.2 | Comparator of controlled trial | No |
| E.8.1.3 | Single blind | No |
| E.8.1.4 | Double blind | Yes |
| E.8.1.5 | Parallel group | No |
| E.8.1.6 | Cross over | No |
| E.8.1.7 | Other | No |

### E.8.2 Comparator of Controlled Trial

| E.8.2.1 | Other medicinal product(s) | No |
| E.8.2.2 | Placebo | Yes |
| E.8.2.3 | Other | No |

| E.8.2.4 | Number of treatment arms in the trial | 4 |
| E.8.2.5 | The trial involves single site in the Member State concerned | Yes |
| E.8.2.6 | The trial involves multiple sites in the Member State concerned | No |

### E.8.3 The trial involves single site in the Member State concerned

| E.8.3.1 | The trial involves single site in the Member State concerned | Yes |

### E.8.4 The trial involves multiple sites in the Member State concerned

| E.8.4.1 | The trial involves multiple sites in the Member State concerned | No |

### E.8.5 The trial involves multiple Member States

| E.8.5.1 | The trial involves multiple Member States | No |

### E.8.6 Trial involving sites outside the EEA

| E.8.6.1 | Trial being conducted both within and outside the EEA | No |
| E.8.6.2 | Trial being conducted completely outside of the EEA | No |
| E.8.6.3 | Trial has a data monitoring committee | No |

| E.8.6.4 | Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial | End of the trial is when all participants successfully finished the three testing sessions. End of trial is when we can successfully determine the effects of baclofen in the treatment of alcohol addiction. |

### E.8.9 Initial estimate of the duration of the trial

| E.8.9.1 | In the Member State concerned years | 1 |
| E.8.9.2 | In the Member State concerned months | 10 |
| E.8.9.3 | In the Member State concerned days | 17 |

### F. Population of Trial Subjects

#### F.1 Age Range

| F.1.1 | Trial has subjects under 18 | No |
| F.1.1.1 | In Utero | No |
| F.1.1.2 | Preterm newborn infants (up to gestational age < 37 weeks) | No |
| F.1.1.3 | Newborns (0-27 days) | No |
| F.1.1.4 | Infants and toddlers (28 days-23 months) | No |
| F.1.1.5 | Children (2-11 years) | No |
| F.1.1.6 | Adolescents (12-17 years) | Yes |
| F.1.1.7 | Adults (18-64 years) | Yes |
| F.1.1.8 | Elderly (>=65 years) | No |

| F.1.2 | Adults (18-64 years) | Yes |
| F.1.2.1 | Number of subjects for this age range: | 250 |

| F.1.3 | Elderly (>=65 years) | No |

### F.2 Gender

| F.2.1 | Female | Yes |
| F.2.2 | Male | Yes |

### F.3 Group of trial subjects

| F.3.1 | Healthy volunteers | No |
| F.3.2 | Patients | Yes |
| F.3.3 | Specific vulnerable populations | Yes |
| F.3.3.1 | Women of childbearing potential not using contraception | No |
| F.3.3.2 | Women of child-bearing potential using contraception | Yes |
| F.3.3.3 | Pregnant women | No |
| F.3.3.4 | Nursing women | No |
| F.3.3.5 | Emergency situation | No |
| F.3.3.6 | Subjects incapable of giving consent personally | No |
| F.3.3.7 | Others | No |

### F.4 Planned number of subjects to be included

| F.4.1 | In the member state | 250 |
| F.4.2 | For a multinational trial | 250 |

### F.5 Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected normal treatment of that condition)

| F.5.1 | Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected normal treatment of that condition) | Subject can choose to continue taking baclofen after the end of the trial. Baclofen is then prescribed by a physician. Furthermore, phone interviews will be held after 3, 6, and 9 month in order to assess use of alcohol and well being. |

### G. Investigator Networks to be involved in the Trial

| G.1 | Investigator Networks to be involved in the Trial | |
| G.2 | N. Review by the Competent Authority or Ethics Committee in the country concerned | |
| G.3 | N. Competent Authority Decision | Authorised |
| G.4 | N. Date of Competent Authority Decision | 2012-02-24 |
| G.5 | N. Ethics Committee Opinion of the trial application | Favourable |
| G.6 | N. Ethics Committee Opinion: Reason(s) for unfavourable opinion | |
| G.7 | N. Date of Ethics Committee Opinion | 2012-10-09 |

### H. End of Trial

| H.1 | End of Trial Status | Ongoing |