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

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A. 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	

B. Sponsor Information		
B.Sponsor: 1		
B.1.1	Name of Sponsor	Academic Medical Centrum
B.1.3.4	Country	Netherlands
B.3.1 and B.3.2	Status of the sponsor	Non-Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:		
B.4.1	Name of organisation providing support	Amsterdams Fonds voor Verslavingsonderzoek
B.4.2	Country	Netherlands
B.5 Contact point designated by the sponsor for further information on the trial		
B.5.1	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

B.5.3.3	Post code	1018 XA
B.5.3.4	Country	Netherlands
B.5.4	Telephone number	00310205256871
B.5.5	Fax number	00310206390279
B.5.6	E-mail	E.M.BerahaMenahem@uva.nl

D. 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.2.1.1.1	Trade name	Baclofen
D.2.1.1.2	Name of the Marketing Authorisation holder	ratiopharm nederland BV
D.2.1.2	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.3.9.4	EV Substance Code	SUB05667MIG
D.3.10	Strength	
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

D.8 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

E. 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		

E.2.1	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.
E.2.2	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
E.2.3	Trial contains a sub-study	No
E.3	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
E.4	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
E.5 End points		
E.5.1	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.
E.5.1.1	Timepoint(s) of evaluation of this end point	after 18 weeks
E.5.2	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.
E.5.2.1	Timepoint(s) of evaluation of this end point	after 18 weeks
E.6 and E.7 Scope of the trial		
E.6	Scope of the trial	
E.6.1	Diagnosis	No
E.6.2	Prophylaxis	No
E.6.3	Therapy	Yes
E.6.4	Safety	Yes
E.6.5	Efficacy	Yes
E.6.6	Pharmacokinetic	No
E.6.7	Pharmacodynamic	No
E.6.8	Bioequivalence	No
E.6.9	Dose response	No
E.6.10	Pharmacogenetic	Yes
E.6.11	Pharmacogenomic	No
E.6.12	Pharmacoeconomic	No
E.6.13	Others	No
E.7	Trial type and phase	
E.7.1	Human pharmacology (Phase I)	No
E.7.1.1	First administration to humans	No
E.7.1.2	Bioequivalence study	No
E.7.1.3	Other	No
E.7.1.3.1	Other trial type description	
E.7.2	Therapeutic exploratory (Phase II)	No
E.7.3	Therapeutic confirmatory (Phase III)	Yes
E.7.4	Therapeutic use (Phase IV)	Yes
E.8 Design of the trial		
E.8.1	Controlled	Yes
E.8.1.1	Randomised	Yes

E.8.1.2	Open	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.8.3	The trial involves single site in the Member State concerned	Yes
E.8.4	The trial involves multiple sites in the Member State concerned	No
E.8.5	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.8.7	Trial has a data monitoring committee	No
E.8.8	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.8.9.1	In the Member State concerned months	10
E.8.9.1	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 (2-11years)	No
F.1.1.6	Adolescents (12-17 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	
F.4.2.2	In the whole clinical 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)	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

N. Review by the Competent Authority or Ethics Committee in the country concerned		
N.	Competent Authority Decision	Authorised
N.	Date of Competent Authority Decision	2012-02-24
N.	Ethics Committee Opinion of the trial application	Favourable
N.	Ethics Committee Opinion: Reason(s) for unfavourable opinion	
N.	Date of Ethics Committee Opinion	2012-10-09

P. End of Trial		
P.	End of Trial Status	Ongoing