Clinical trial results:
Baclofen for the Treatment of Alcohol Dependence

Summary

EudraCT number	2010-021861-62
Trial protocol	DE
Global end of trial date	20 May 2014

Results information

Result version number	v1 (current)
This version publication date	18 April 2022
First version publication date	18 April 2022

Trial information

Trial identification

Sponsor protocol code	BACLAD

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01266655
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Charité - Universitätsmedizin Berlin
Sponsor organisation address	Charitéplatz 1, Berlin, Germany,
Public contact	Department of Psychiatry, Campus Charité Mitte, Charité - Universitätsmedizin Berlin, Germany, Department of Psychiatry, Campus Charité Mitte, Charité - Universitätsmedizin Berlin, Germany, +49 30-450-517002, chefsek-psychiatrie-ccm@charite.de
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 March 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 May 2014
Global end of trial reached?	Yes
Global end of trial date	20 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy and safety of individually titrated high-dose baclofen (up to 270 mg/d) in alcohol-dependent patients in a double-blind, randomized and placebo-controlled trial.
Multiple primary outcome measures: (1) total abstinence and (2) cumulative abstinence duration during the high-dose phase.

Protection of trial subjects:

The trial was conducted in conformance with Good Clinical Practice (GCP) standards and applicable local statutes and regulations regarding ethical committee review, informed consent and the protection of human subjects participating in biomedical research. The following additional measures, defined for this individual trial, were in-place for the protection of the trial subjects:
13 to 17 visits throughout the study (depending on the individually titrated high-dose). Additionally, telephone visits were performed during the titration and tapering phases after each dosing step.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 March 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 56
Worldwide total number of subjects	56
EEA total number of subjects	56

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	56

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at the outpatient unit of the Department of Psychiatry and Psychotherapy at Charité - Universitätsmedizin Berlin between March 2011 and May 2014.

Pre-assignment

Screening details:

A total of 93 alcohol-dependent subjects entered the screening period.

Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received placebo (30-270 mg/d) for up to 20 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Patients received placebo 5-90 mg t.i.d.

Arm title	Baclofen

Arm description:

Subjects received baclofen (30-270 mg/d) for up to 20 weeks.

Arm type	Experimental
Investigational medicinal product name	Baclofen
Investigational medicinal product code	1134-47-0
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Patients received baclofen 5 to 90 mg t.i.d.

Number of subjects in period 1	Placebo	Baclofen
Started	28	28
Completed	4	12
Not completed	24	16
Relapse	18	10
Participant choice	3	1
Protocol violation	1	-
Adverse event, non-fatal	-	2
Lost to follow-up	2	3

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo (30-270 mg/d) for up to 20 weeks.	
Reporting group title	Baclofen
Reporting group description:	
Subjects received baclofen (30-270 mg/d) for up to 20 weeks.	

Reporting group values	Placebo	Baclofen	Total
Number of subjects	28	28	56
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	45.6	47.4	
standard deviation	± 7	± 7	-
Gender categorical Units: Subjects			
Female	9	8	17
Male	19	20	39

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received placebo (30-270 mg/d) for up to 20 weeks.	
Reporting group title	Baclofen
Reporting group description: Subjects received baclofen (30-270 mg/d) for up to 20 weeks.	

Primary: Total abstinence during the high-dose phase

End point title	Total abstinence during the high-dose phase
End point description:	
End point type	Primary
End point timeframe: 12 weeks.	

End point values	Placebo	Baclofen		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	28		
Units: number of patients	5	15		

Statistical analyses

Statistical analysis title	Non-parametric exact Wilcoxon-Mann-Whitney test
Comparison groups	Baclofen v Placebo
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 24 weeks.	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	own
Dictionary version	1
Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Baclofen
Reporting group description: -	

Serious adverse events	Placebo	Baclofen	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 28 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo	Baclofen	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 28 (100.00%)	28 / 28 (100.00%)	
Cardiac disorders			
Hypertension			
subjects affected / exposed	2 / 28 (7.14%)	3 / 28 (10.71%)	
occurrences (all)	2	3	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 28 (25.00%)	4 / 28 (14.29%)	
occurrences (all)	7	4	
Tingling sensation			
subjects affected / exposed	0 / 28 (0.00%)	3 / 28 (10.71%)	
occurrences (all)	0	3	
Pain diverse			

subjects affected / exposed	8 / 28 (28.57%)	4 / 28 (14.29%)	
occurrences (all)	8	4	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	7 / 28 (25.00%)	13 / 28 (46.43%)	
occurrences (all)	7	13	
Ear and labyrinth disorders			
Vertigo/dizziness			
subjects affected / exposed	0 / 28 (0.00%)	5 / 28 (17.86%)	
occurrences (all)	0	5	
Eye disorders			
Visualdisturbances			
subjects affected / exposed	2 / 28 (7.14%)	5 / 28 (17.86%)	
occurrences (all)	2	5	
Gastrointestinal disorders			
Gastrointestinal symptoms			
subjects affected / exposed	3 / 28 (10.71%)	1 / 28 (3.57%)	
occurrences (all)	3	1	
Psychiatric disorders			
Sleep disturbances			
subjects affected / exposed	4 / 28 (14.29%)	9 / 28 (32.14%)	
occurrences (all)	4	9	
Depressed mood/anxiety			
subjects affected / exposed	2 / 28 (7.14%)	3 / 28 (10.71%)	
occurrences (all)	2	3	
Renal and urinary disorders			
Urgency			
subjects affected / exposed	3 / 28 (10.71%)	1 / 28 (3.57%)	
occurrences (all)	3	1	
Musculoskeletal and connective tissue disorders			
Muscle pain			
subjects affected / exposed	3 / 28 (10.71%)	0 / 28 (0.00%)	
occurrences (all)	3	0	
Fasciculations			
subjects affected / exposed	1 / 28 (3.57%)	4 / 28 (14.29%)	
occurrences (all)	1	4	
Infections and infestations			

Common cold/infection subjects affected / exposed occurrences (all)	11 / 28 (39.29%) 11	1 / 28 (3.57%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26048580