



Clinical trial results:

Internet-based cognitive behavior therapy in combination with D-Cycloserine for Obsessive Compulsive Disorder: A double blinded randomized controlled trial

Summary

EudraCT number	2011-002819-28
Trial protocol	SE
Global end of trial date	09 December 2016

Results information

Result version number	v1 (current)
This version publication date	04 June 2021
First version publication date	04 June 2021

Trial information

Trial identification

Sponsor protocol code	OCDDCS001
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Stockholms Läns Landsting
Sponsor organisation address	M46 Mottagningen för tvångssyndrom, Huddinge sjukhus, Psykiatri Sydväst, Huddinge, Sweden, 14186
Public contact	Christian Rück, Stockholms Läns Landsting, christian.ruck@ki.se
Scientific contact	Christian Rück, Stockholms Läns Landsting, christian.ruck@ki.se

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	27 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 May 2015
Global end of trial reached?	Yes
Global end of trial date	09 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary aim with the study is to investigate whether D-Cycloserine (DCS) gives incremental effects to Internet-based cognitive behavior therapy (ICBT) in terms of reduced Obsessive Compulsive Disorder (OCD) symptoms at post-treatment and follow-up.

Protection of trial subjects:

Continuous monitoring of the participants health and well-being by study clinicians and monitoring of side-effects specifically, applying action plan when necessary.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 April 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research, Efficacy
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 128
Worldwide total number of subjects	128
EEA total number of subjects	128

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)	126
From 65 to 84 years	2

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	128
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Number of subjects completed	128
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Period 1

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

Are arms mutually exclusive?	Yes
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Arm title	ICBT+DCS
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	D-Cycloserine (DCS)
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Capsule
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Routes of administration	Oral use
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Dosage and administration details:

1 capsule of DCS 50 mg 1 time per week in 5 weeks

Arm title	ICBT+Placebo
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Arm description: -

Arm type	Placebo
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Investigational medicinal product name	Placebo
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Capsule
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Routes of administration	Oral use
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Dosage and administration details:

1 capsule of placebo 50 mg 1 time per week in 5 weeks

Number of subjects in period 1	ICBT+DCS	ICBT+Placebo
Started	64	64
Completed	64	64

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	128	128	
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	34.76		
full range (min-max)	19 to 71	-	
Gender categorical			
Units: Subjects			
Female	74	74	
Male	54	54	

End points

End points reporting groups

Reporting group title	ICBT+DCS
Reporting group description: -	
Reporting group title	ICBT+Placebo
Reporting group description: -	

Primary: Difference in reduction on Y-BOCS between experimental and placebo conditions fro baseline to post-treatment (12 weeks)

End point title	Difference in reduction on Y-BOCS between experimental and placebo conditions fro baseline to post-treatment (12 weeks)
End point description:	
End point type	Primary
End point timeframe:	
0-12 weeks	

End point values	ICBT+DCS	ICBT+Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	64	64		
Units: OCD symptoms assessed using the Y-BOCS (
arithmetic mean (standard deviation)	13.86 (± 6.50)	11.77 (± 5.95)		

Statistical analyses

Statistical analysis title	Mixed-model analysis
Comparison groups	ICBT+DCS v ICBT+Placebo
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.75
Method	Mixed models analysis
Parameter estimate	Slope
Point estimate	-0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.13
upper limit	0.47

Adverse events

Adverse events information

Timeframe for reporting adverse events:

0-12 weeks + 3-months follow-up

Assessment type	Systematic
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Dictionary used

Dictionary name	Psychiatrist labled
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Dictionary version	na
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Reporting groups

Reporting group title	DCS-arm
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Reporting group description: -

Reporting group title	Placebo arm
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Reporting group description: -

Serious adverse events	DCS-arm	Placebo arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 64 (0.00%)	0 / 64 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	DCS-arm	Placebo arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 64 (51.56%)	43 / 64 (67.19%)	
Injury, poisoning and procedural complications			
Car crash (non-fatal)			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Nose bleeding			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Irregular heart beat			

subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	0 / 64 (0.00%) 0	
Nervous system disorders			
Nightmares			
subjects affected / exposed	4 / 64 (6.25%)	0 / 64 (0.00%)	
occurrences (all)	4	0	
Dizziness			
subjects affected / exposed	1 / 64 (1.56%)	1 / 64 (1.56%)	
occurrences (all)	1	1	
Sleep difficulties			
subjects affected / exposed	1 / 64 (1.56%)	1 / 64 (1.56%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Feeling ill			
subjects affected / exposed	1 / 64 (1.56%)	2 / 64 (3.13%)	
occurrences (all)	1	2	
Head ache			
subjects affected / exposed	1 / 64 (1.56%)	2 / 64 (3.13%)	
occurrences (all)	1	2	
Tiredness			
subjects affected / exposed	2 / 64 (3.13%)	2 / 64 (3.13%)	
occurrences (all)	2	2	
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 64 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Gastrointestinal symptoms			
subjects affected / exposed	0 / 64 (0.00%)	4 / 64 (6.25%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Viral nasopharyngitis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			

Itch			
subjects affected / exposed	0 / 64 (0.00%)	2 / 64 (3.13%)	
occurrences (all)	0	2	
Sweatiness			
subjects affected / exposed	0 / 64 (0.00%)	2 / 64 (3.13%)	
occurrences (all)	0	2	
Psychiatric disorders			
Concentration difficulties			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	
occurrences (all)	0	1	
Paranoia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	
occurrences (all)	0	1	
Suicidal thoughts			
subjects affected / exposed	1 / 64 (1.56%)	1 / 64 (1.56%)	
occurrences (all)	1	1	
Increased anxiety			
subjects affected / exposed	9 / 64 (14.06%)	14 / 64 (21.88%)	
occurrences (all)	9	14	
Increased depressive symptoms			
subjects affected / exposed	5 / 64 (7.81%)	3 / 64 (4.69%)	
occurrences (all)	5	3	
Irritability			
subjects affected / exposed	2 / 64 (3.13%)	3 / 64 (4.69%)	
occurrences (all)	2	3	
Panic attack			
subjects affected / exposed	2 / 64 (3.13%)	2 / 64 (3.13%)	
occurrences (all)	2	2	
Musculoskeletal and connective tissue disorders			
Migraine			
subjects affected / exposed	0 / 64 (0.00%)	1 / 64 (1.56%)	
occurrences (all)	0	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