# 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 |

**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 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 128 |
| Number of subjects completed | 128 |

### Period 1

| | |
|---|---|
| Period 1 title | Overall trial (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** | ICBT+DCS |

Arm description: -

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | ICBT+Placebo |

Arm description: -

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

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<br>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<br>Units: years | | | |
| arithmetic mean | 34.76 | | |
| full range (min-max) | 19 to 71 | - | |
| Gender categorical<br>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 analisys |
|---|---|
| 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 |
| **Dictionary used** | |
| Dictionary name | Psychiatrist labled |
| Dictionary version | na |
| **Reporting groups** | |
| Reporting group title | DCS-arm |
| Reporting group description: - | |
| Reporting group title | Placebo arm |
| 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 | 1 / 64 (1.56%) | 0 / 64 (0.00%) | |
| occurrences (all) | 1 | 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 nasopharingitys | | | |
| 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