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Nordic Long-term Obsessive compulsive disorder (OCD) Treatment Study

Submission date
20/10/2007

Recruitment status
No longer recruiting

Registration date
19/03/2008

Overall study status
Completed

Last Edited
10/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Pediatric Obsessive Compulsive Disorder (OCD) is a serious and often chronic disorder involving obsessive and excessive fears, and behaviours (i.e., rituals) that aim to neutralize the fears and dangers. The symptoms lead to impairment and reduced quality of life. There is impressive evidence for the effectiveness of Cognitive Behaviour Therapy (CBT) with exposure to the feared situations and response prevention of the rituals. Moreover, CBT gives good symptom relief in many, better than drug treatments (i.e., serotonin reuptake inhibiting drugs [SSRIs]). SSRI treatment also has an impressive evidence base. However, little is known about what treatments to offer in children and adolescents who do not benefit from CBT. So, our study aims at investigating whether continued CBT or a switch to sertraline (an SSRI) is best in these non-responding children and adolescents. However, we are also interested in investigating whether regular child and adolescent clinicians can be taught such CBT and be as efficient as psychotherapists working in specialized OCD clinics.

Who can participate?
Children and adolescents, aged 7-17 years, with moderate to severe OCD.

What does the study involve?
Following a thorough baseline diagnostic work-up, patients participate in 14 sessions of CBT. Assessments are made also at the 7th and 13th weeks of the therapy. Youngsters who do not benefit from CBT are then randomly allocated to either sertraline or to continued CBT.

What are the possible benefits and risks of participating?
The participants receive state-of-the-art CBT and drug treatment which increase the chance of symptom relief, while the risks are small.

Where is the study run from?
Three Scandinavian countries (Sweden, Norway and Denmark) contribute. The Center for Child and Adolescent Mental Health, Eastern and Southern Norway (RBUP) is the data center.

When is the study starting and how long is it expected to run for?
The study started in 2008, has now stopped inclusion, and is currently working on a long-term follow-up scheme to study whether gains from therapy are durable.

Who is funding the study?
All participating centers finance their own contribution with the aid of the local hospital or grants from research foundations. At RBUP, grants from research foundations have covered costs associated with graduate students. RBUP and the Norwegian Research Council have contributed to an electronic data capture system.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NordLOTS protocol 1.2

Study information

Scientific Title
Nordic Long-term Obsessive compulsive disorder (OCD) Treatment Study

Acronym
NordLOTS

Study objectives
Children and adolescents with obsessive compulsive disorder (OCD) who do not respond to a course of cognitive behaviour therapy (CBT) will benefit equally from sertraline and from continued CBT. Identification of CBT versus sertraline responders is possible. Non responders to CBT and sertraline will benefit from aripiprazol augmentation.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Denmark, Institutional Review Board (IRB) (Den videnskabsetiske komité for Region Midtjylland), ref: 20070140
2. Sweden, IRB, 04/02/2008
3. Norway, IRB, 10/03/2008

Study design
Randomized active controlled trial with three steps:
1: Open uncontrolled
2: Randomised and controlled
3: Open uncontrolled

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive compulsive disorder

Interventions
Step 1: Cognitive behaviour therapy (CBT)
Step 2: Sertraline plus CBT support (less intensive CBT) or intensive CBT
Step 3: Sertraline plus CBT support plus aripiprazol

Non-responders to CBT are randomised to continued CBT or sertraline with CBT support. CBT plus sertraline non-responders are treated un-controlled with aripiprazol. Outcome is studied for 36 months.

Dosing schedule of sertraline:
Week 0: no dose given
Week 1: 25 mg for 3 days, then 50 mg (range: 25 - 50 mg)
Week 2: 75 mg (range: 50 - 75 mg)
Weeks 3 - 4: 100 mg (range: 75 - 100 mg)
Weeks 5 - 7: 150 mg (range: 75 - 150 mg)
Weeks 8 - 12: 200 mg (range: 75 - 200 mg)
Weeks 6 - 12: 200 mg (range: 75 - 200 mg)

Dosing schedule of aripiprazol:
Week 0: no dose given
Week 1: 2.5 mg for 7 days (range: 2.5 mg)
Weeks 2 - 4: 5 mg (range: 2.5 - 5 mg)
Weeks 5 - 7: 7.5 mg (range: 2.5 - 7.5 mg)
Weeks 8 - 12: 10 - 20 mg (range: 2.5 - 20 mg)
Weeks 12 onwards: 2.5 - 20 mg

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sertraline, aripiprazole

Primary outcome(s)
1. CYBOCS
2. Clinical Global Impression Scale
3. Clinical Global Improvement Scale
4. Children's OCD Impact Scale
Outcomes measured (approximately) at weeks 0, 7, 13, and months 6, 12, 24, 36.

Key secondary outcome(s)
1. Screen for Child Anxiety Related Disorders Revised (SCARED-R)
2. Mood and Feelings Questionnaire (MFQ)
3. Children's Global Assessment Scale (CGAS)
4. Child Behaviour Checklist (CBCL)
5. Family Accomodation Scale (FAS)
6. Need to add another treatment
Outcomes measured (approximately) at weeks 0, 7, 13, and months 6, 12, 24, 36.

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Patients 7 - 17 years of age
2. Moderate-severe obsessive compulsive disorder according to Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM IV). Severity is defined by Children's Yale-Brown Obsessive Compulsive Scales (CY-BOCS) scores of 16 or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
17 years

Sex
All

Total final enrolment
269

Key exclusion criteria
1. Co-morbidity has not higher treatment priority (e.g. psychosis, anorexia nervosa, severe depression with suicidality, an autistic disorder or Asperger's syndrome)
2. Pervasive developmental disorders (PDD) not otherwise specified (NOS) is allowed if Clinical Global Impression (CGI) score for the PDD is less than or equal to 3 and CGI for the PDD NOS is less than or equal to CGI for the OCD
3. Mental retardation (intelligence quotient [IQ] less than 70)
4. Patients have not been treated with selective serotonin reuptake inhibitor (SSRI) or CBT for their OCD during the last year
5. If the patient is of non-Nordic ethnicity both the patient and one parent must speak a Nordic language

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Denmark

Norway

Sweden

Study participating centre
Gullhaug Torg 4B
Oslo
Norway
0484

Sponsor information

Organisation
The Centre for Child and Adolescent Mental Health, Eastern and Southern Norway (R.BUP) (Norway)

ROR
https://ror.org/042s03372

Funder(s)

Funder type
Research organisation

Funder Name
The Centre for Child and Adolescent Mental Health, Eastern and Southern Norway (Regionsenter for Barn og Unges Psykiske helse [R.BUP]) (Norway) - for the Nordic coordination

Funder Name
The participating clinics finance their participation from local funding agencies

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/10/2014		Yes	No
Results article		01/03/2015		Yes	No
Results article		01/11/2019	21/04/2020	Yes	No
Results article		01/04/2021	19/04/2021	Yes	No
Results article	Quality of life results	01/04/2021	22/04/2021	Yes	No
Results article	Relapse rates following remission	03/12/2023	11/12/2023	Yes	No
Results article		09/07/2025	10/07/2025	Yes	No