ISRCTN63930220 https://doi.org/10.1186/ISRCTN63930220

Aripiprazole shows comparable efficacy to Haloperidol and better tolerability in paediatric Tic disorders

Submission date	Recruitment status	[ ] Prospectively registered
16/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/06/2008	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
ArHdTic

Study objectives
Tics are defined as rapid and repetitive muscle contractions resulting in movements or vocalisations that are experienced as involuntary. Tic disorders are a group of neuropsychiatic disorders that generally begin in childhood or adolescence and may be constant or wax and wane over time.

Aripiprazole is a candidate atypical antipsychotic for patients with tic disorders due to its unique pharmacodynamic property of dopamine partial agonistic activity with fewer and milder side effects. This study was conducted to determine whether aripiprazole has comparable efficacy to haloperidol, the most widely used typical antipsychotic in the treatment of tic disorders, but which has a higher tolerability.

The pilot study and efficacy study of this trial have been published as follows:
1. A pilot study of aripiprazole in children and adolescents with Tourette's disorder (http://www.ncbi.nlm.nih.gov/pubmed/16958578)
2. An open-label study of the efficacy and tolerability of aripiprazole for children and adolescents with tic disorders (http://www.ncbi.nlm.nih.gov/pubmed/17685747)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Review Board of Asan Medical Centre, Seoul, South Korea on the 30th July 2005 (ref: 2005-0163).

Study design
Single-centre, open, parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tic disorders

Interventions
In the aripiprazole group, a child psychiatrist initially prescribed 5.0 mg/d of aripiprazole, and then increased the dose in 5.0 mg/d increments as tolerated at visits every two weeks. The dose was reduced by 2.5 mg/d to 5.0 mg/d when intolerable side effects emerged. The maximum allowable dose was 20 mg/d.

In the haloperidol group, haloperidol was titrated from a commencing dose of 0.75 mg/d to a maximum tolerated dose of 4.5 mg/d in 1.5 - 3.0 mg increments at visits every other week

The total duration of treatment and follow-up were eight weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aripiprazole, haloperidol

Primary outcome measure
Yale Global Tic Severity Scale (YGTSS): the YGTSS is a semi-structured clinical interview designed to assess current tic severity, which yields three summary scores.

Both primary and secondary outcomes were measured at every visit (baseline, two weeks, four weeks, six weeks, eight weeks).

Secondary outcome measures
1. The Clinical Global Impressions-Improvement Scale (CGI-I)
2. The CGI-Severity of Illness Scale (CGI-S)
3. The Extrapyramidal Symptom Rating Scale (ESRS)

Both primary and secondary outcomes were measured at every visit (baseline, two weeks, four weeks, six weeks, eight weeks).

Overall study start date
01/08/2005

Completion date
30/03/2007

Eligibility

Key inclusion criteria

1. Aged 6 - 18 years
2. Gender: male or female
3. Diagnosis: tic disorders according to the Korean version of the Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version (KSADS-PL)
4. Severity: total tic scores greater than or equal to 22 on the Korean version of the Yale Global Tic Severity Scale

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Current mood disorders
2. Psychotic symptoms
3. Anxiety disorders except obsessive-compulsive disorder, which is the most common comorbid anxiety disorder in tic patients
4. Subjects with an intelligence quotient (IQ) of 70 or less by using the Korean version of the Wechsler Intelligence Scale for Children-Revised
5. Previous or current seizure episodes, electroencephalogram (EEG) abnormalities
6. Subjects had used aripiprazole previously
7. Any significant medical problems
8. Pregnancy

Date of first enrolment
01/08/2005

Date of final enrolment
30/03/2007

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Psychiatry
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Sponsor information

Organisation
Asan Medical Centre (South Korea)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.seoul.kr/eng/index.jsp

ROR
https://ror.org/03s5q0090

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (South Korea)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration