A Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Safety and Efficacy of Fixed-dose Once-daily Oral Aripiprazole in Children and Adolescents with Tourette*s Disorder.

Published: 07-01-2013
Last updated: 24-04-2024

Primary: To compare the efficacy of aripiprazole with placebo in the suppression of tics in children and adolescents (7-17 years) with a diagnosis of Tourette*s Disorder. The primary efficacy measure is change from Baseline to endpoint (Week 8) on...

Ethical review	Not approved
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON36846

Source
ToetsingOnline

Brief title
Safety and Efficacy of Oral Aripiprazole

Condition

- Cognitive and attention disorders and disturbances

Synonym
Tourette's syndrome; Tourette tics

Research involving
Human

Sponsors and support

Primary sponsor: Otsuka Pharmaceutical Development & Commercialization, Inc.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Abilify, Aripiprazole, CAS 129722-12-9, OPC-14597

Outcome measures

Primary outcome

Primary Endpoint: Change from Baseline to endpoint (Week 8) in YGTSS TTS.

Secondary outcome

Key Secondary Endpoints: Mean CGI-TS Change score at endpoint (change score

obtained from CGI-TS improvement scale assessment)

Study description

Background summary

There are a very limited number of medications approved for the treatment of Tourette*s Disorder, including the typical neuroleptics haloperidol and pimozide. These medications have been available for decades and exhibit all the known side-effects of the typical neuroleptic medications. Currently, the alpha-2 receptor agonist clonidine is the first-line treatment for Tourette*s Disorder; however, the level of efficacy is limited and the side effect of sedation is not well tolerated.

See Protocol 31-12-293 Version 2.0 16 October 2012 Section 2.1 Trial Rationale

Study objective

Primary: To compare the efficacy of aripiprazole with placebo in the suppression of tics in children and adolescents (7-17 years) with a diagnosis of Tourette*s Disorder. The primary efficacy measure is change from Baseline to endpoint (Week 8) on the Total Tic score (TTS) of the Yale Global Tic Severity Scale (YGTSS). The secondary efficacy measure is the Clinical Global Impressions Scale for Tourette*s Syndrome (CGI-TS).

Secondary: To evaluate the safety and tolerability of aripiprazole Once-daily treatment with oral tablets in children and adolescents with a diagnosis of Tourette*s Disorder.

(See Protocol 31-12-293 Version 2.0 16 October 2012 Section 2.3 Trial Objectives)

Study design

Study 31-12-293 is a Phase 3, multicenter, randomized, double-blind, placebo-controlled trial designed to assess the safety and efficacy of fixed-dose oral aripiprazole once-daily tablets in children and adolescents, 7-17 years of age at Screening (the time at which they sign the informed consent), with Tourette*s Disorder. A total of 126 subjects in 2 weight groups (low: < 50 kg; high: >= 50 kg) will be randomized to aripiprazole low dose, aripiprazole high dose, or placebo in a 1:1:1 ratio. The aripiprazole low dose is 5.0 mg/day for the low-weight group and 10.0 mg/day for the high-weight group; the aripiprazole high dose is 10.0 mg/day for the low-weight group and 20.0 mg/day for the high-weight group.

For full overview see Protocol 31-12-293 Version 2.0 16 October 2012 Section 3 Trial Design

Study burden and risks

The most common side effects may include headache, nausea, vomiting, constipation, anxiety, insomnia (problems sleeping), dizziness (lightheadedness), akathisia (unpleasant sensations of "inner" restlessness that make you unable to sit still or remain motionless), restlessness. The most common side effects in pediatric patients may include: vomiting, extrapyramidal disorder (extreme restlessness, involuntary movements, and uncontrollable speech), fatigue (feeling tired), increased appetite, insomnia (problems sleeping), headache, nausea, nasopharyngitis (swelling of nasal passages), somnolence (sleepiness) and increased weight.

There have been a few reports of high blood sugar in subjects treated with aripiprazole. Your blood sugar level will be monitored closely.
Inactive ingredients of aripiprazole tablets include lactose. Please discuss with your trial physician if you think that your child has lactose intolerance (problem tolerating milk and other dairy products). In clinical trials with aripiprazole, the incidence of this effect was comparable to placebo.

(Source Risk section of Main Study ICF Version 2.0 Netherlands Template in English dated 29NOV2012)

Contacts

Public
Otsuka Pharmaceutical Development & Commercialization, Inc.

Research Boulevard, Rockville 2440
Maryland 20850
US
Scientific
Otsuka Pharmaceutical Development & Commercialization, Inc.

Research Boulevard, Rockville 2440
Maryland 20850
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. The subject is a male or female child or adolescent, 7-17 years of age (inclusive) at the time of signing the informed consent/assent.
2. The subject meets current DSM-IV-TR diagnostic criteria for Tourette*s Disorder, as confirmed by the K-SADS-PL, including the Diagnostic Supplement 5 (Substance Abuse and Other Diseases, ie, Tic Disorders).
3. The subject has a TTS >= 20 on the YGTSS at Screening and Baseline (randomization).
4. The subject, a caregiver, and the investigator must all agree that the presenting tic symptoms cause impairment in the subject's normal routines, which include academic achievement, occupational functioning, social activities, and/or relationships.
5. Females of childbearing potential (defined by menarche and not having undergone surgical sterilization/hysterectomy) must have a negative pregnancy test, must be practicing

acceptable double-barrier methods of contraception (or can confirm abstinence at each scheduled visit), and must not be pregnant or lactating.
6. Written informed consent must be obtained from a legally acceptable representative (eg, guardian or caregiver), in accordance with local law and the requirements of the trial center*s institutional review board (IRB) or independent ethics committee (IEC), prior to the initiation of any protocol-required procedures. In addition, the subject, as required by the trial center*s IRB/IEC, must provide informed assent at Screening and as such must be able to understand that he or she can withdraw from the trial at any time.
7. The subject and the designated guardian(s) or caregiver(s) are able to comprehend and satisfactorily comply with the protocol requirements, as evaluated by the investigator.

Exclusion criteria

1. The subject presents with a clinical presentation and/or history that is consistent with another neurologic condition that may have accompanying abnormal movements.;These include, but are not limited to:
• Transient Tic disorder
• Huntington's disease
• Parkinson's disease
• Sydenham's chorea
• Wilson's disease
• Mental retardation
• Pervasive developmental disorder
• Traumatic brain injury
• Stroke
• Restless Legs Syndrome;2. The subject has a history of schizophrenia, bipolar disorder, or other psychotic disorder.
3. Subjects who receive psychostimulants for the treatment of ADD/ADHD and who have developed and/or had exacerbations of the tic disorder after the initiation of stimulant treatment (Note that subjects with ADD/ADHD who are treated with psychostimulants and have not developed new tics or a worsening of their current tics can be included if all other enrollment obligations are met).
4. The subject currently meets DSM-IV-TR criteria for a primary mood disorder.
5. The subject has severe obsessive-compulsive disease (OCD), as evidenced by a Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) score > 16.;Other criteria see Protocol 31-12-293 Version 2.0 16 October 2012 Section 3.4.3 Exclusion Criteria

Study design

Design

Study phase: 3

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	6
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Aripiprazole
Generic name:	Abilify
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-01-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	13-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-003488-23-NL
ClinicalTrials.gov	NCT01727700
CCMO	NL42749.042.12