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A prospective Longitudinal trial of the effect of Atomoxetine on cognitive, educational, behavioural, social and emotional wellbeing in students with Attention Deficit Hyperactivity Disorder

Submission date
02/11/2006

Registration date
20/11/2006

Last Edited
20/11/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Protocol serial number
LP0349029

Study information

Scientific Title

Acronym
LAtADHD

Study objectives
It is hypothesised that over a period of 26 weeks' administration of atomoxetine, students with Attention Deficit Hyperactivity Disorder (ADHD) will demonstrate:
1. Improvement in the cognitive functions of working memory, verbal ability and cognitive efficiency
2. Improved executive functioning capacity
3. Improvement in their educational achievements in reading, mathematics, spelling and written compostion.
4.Improvement in their depression and anxiety ratings.
5. Improvement in their social skills and perceptions of the classroom learning environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the Curtin University Human Research Ethics Committee, (Approval Ref No. 28/2005), and complies with all requirements of the Australian National Health and Medical Research Committee.

Primary study design
Interventional

Study design
Prospective longitudinal study, with a control group of children without ADHD, matched for age and gender and within the same school class as the children with ADHD

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder

Interventions
Administration of atomoxetine for 26 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Atomoxetine

Primary outcome(s)
1. Cognitive functioning, working memory, verbal ability and cognitive efficiency
2. Executive functioning (teacher and parent ratings)
3. Educational achievement

Key secondary outcome(s)
1. Depression (child, parent, teacher ratings)
2. Anxiety (child and parent ratings)
3. Social skills (teacher and parent ratings)
4. Perceptions of learning environment (child ratings)

Completion date
01/11/2007

Eligibility

Key inclusion criteria
1. Boys and girls aged seven to 15 years
2. Meet the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria for ADHD, as determined by the referring paediatrician or child psychiatrist
3. Participants are naive to atomoxetine medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
15 Years

Sex
All

Key exclusion criteria
1. A history of bipolar or psychotic disorder
2. Tourettes syndrome
3. Substance abuse
4. Serious medical illness
5. Intellectual disability (Intelligence Quotient [IQ] less than 70)
6. Pregnancy
7. Non compliance with research protocol

Date of first enrolment
01/11/2006

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
Australia

Study participating centre
Department of Education
Perth, WA
Australia
6845

Sponsor information

Organisation
Australian Research Council (Australia)

ROR
https://ror.org/05mmh0f86

Funder(s)

Funder type
Research council

Funder Name
Australian Research Council (ARC) linkage grant (ref LP0349029), which includes:

Funder Name
ARC funding (AUD 173,000)

Funder Name

West Australian Dept of Education (AUD 15,000)

Funder Name
Association of Independent School of Western Australia (AUD 15,000)

Funder Name
Westmead Children's Hospital Education Research Institute (AUD19,500)

Funder Name
Eli Lilly Australia Pty Ltd (AUD 45,000)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration