ISRCTN25691213 https://doi.org/10.1186/ISRCTN25691213

Atomoxetine for attention deficit hyperactivity disorder (ADHD) in children with special educational needs

Submission date	Recruitment status	[ ] Prospectively registered
19/06/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/10/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2017	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
2008-004827-44

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Open label randomised trial of atomoxetine for attention deficit hyperactivity disorder (ADHD) in children with special educational needs

Acronym
HSEN - ATOM

Study objectives
1. What is the efficacy of atomoxetine in reducing the symptoms and features of attention deficit hyperactivity disorder (ADHD) in children with moderate and severe learning disabilities who also have ADHD?
2 What is the adverse effect profile associated with atomoxetine treatment in children with learning disabilities?

Both these questions will be addressed in children who have tried stimulant treatment but for whom there is either inadequate symptomatic improvement or unacceptable adverse effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Multicentre Research Ethics Committee, 22/10/2008, ref: 08/H1102/86

Study design
Randomised open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD), mental retardation (intellectual disability)

Interventions
40 children between ages 7 and 15 years with moderate-severe learning disability and hyperkinetic disorder will be invited to take part in a open label trial of atomoxetine lasting 16 weeks. Medication dosage for atomoxetine will be individually optimised, balancing reduction in hyperkinetic symptoms against side effects.

Participants will be given daily doses of atomoxetine orally that will be titrated up to a therapeutic dose over a period of two weeks. Initially atomoxetine 0.5 mg/kg (starting dose) will be prescribed for one week, followed by a week of 0.8 mg/kg (low dose). A usual dose of atomoxetine 1.2 mg/kg daily will be carried on after two weeks. Selection of optimal dose will be based on adverse effects and behavioural response. For participants showing less than "much improvement" on the CGI-Improvement (CGI-I) scale at the end of week 8 without presenting adverse effects, may have a further dose increase to 1.4 mg/kg/day (high dose).

Treatment response will be determined by comparing baseline behaviour with that at the end of the 16 weeks. The trial will end at 16 weeks post-randomisation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Atomoxetine

Primary outcome measure
Conners parent and teachers questionnaires, short form: ADHD and hyperactivity indices (parent and teacher), measured at baseline and week 16.

Secondary outcome measures
Measured at baseline and week 16:
1. Adverse events (other behaviours questionnaire plus any others noted)
2. Aberrant Behaviour Checklist
3. Developmental Behaviour Questionnaire
4. Clinical Global Impressions Scale

Overall study start date
01/08/2009

Completion date
31/12/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria

1. Aged 7 - 15 years, either sex
2. Diagnosis of attention deficit hyperactivity disorder (ADHD)
3. Full-scale intelligence quotient (IQ) 30 - 69 or age equivalent estimate
4. Did not respond to methylphenidate either at high dose or because dose limited by unacceptable adverse effects
5. Living in catchment area of one of the participating centres
6. Child in stable care situation
7. Child regularly attending school (more than 75% of last school term)

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Child currently taking atomoxetine
2. A clear-cut history of intolerance to atomoxetine or concomitant use of monoamine oxidase (MAO) medication or narrow angle glaucoma that represent absolute contradictions to the use of atomoxetine
3. Severe limitation of child's mobility
4. Presence of a degenerative disorder
5. Medical conditions that may preclude the use of atomoxetine or may confound outcome measures, including:
5.1. Poorly controlled or uncontrolled epilepsy
5.2. History of significant cardiovascular disease
5.3. History of psychotic, bipolar or severe obsessive compulsive disorder
6. Child on neuroleptic medication (must be withdrawn for 2 months prior to trial assessment)
7. Child poses a significant risk of suicidal or homicidal behaviour
8. Another child in the family/household already enrolled in this study
9. Ongoing child protection concerns

Date of first enrolment
01/08/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Program Grant for Applied Research (PGfAR)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No