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A double-blind, placebo-controlled trial of methylphenidate in children with hyperkinetic disorder and moderate-severe learning disabilities

Submission date
10/03/2006

Recruitment status
No longer recruiting

Registration date
09/05/2006

Overall study status
Completed

Last Edited
16/01/2014

Condition category
Mental and Behavioural Disorders

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

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
CT2004-1

Study information

Scientific Title

Acronym
HSEN

Study objectives
1. What is the efficacy of methylphenidate, under conditions of individual dose optimization, in reducing the symptoms of attention deficit hyperactivity disorder (ADHD) among children with moderate and severe learning disabilities?
2. What is the adverse effects profile associated with methylphenidate treatment amongst children with learning disabilities and which children are at greater risk of developing side effects?
3. What are the predictors of good versus poor responders to treatment? In particular:
a. Are those with severe as opposed to moderate learning disabilities less likely to show a good response?
b. Presence of autistic symptoms

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Multicentre Research Ethics Committee: MREC 04/01/013

Study design
Randomized controlled trial stratified for severity of learning disability (30-49 versus 50-69).

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperkinetic disorder, mental retardation (intellectual disability)

Interventions
180 children between ages 7 and 15 years with moderate-severe learning disability and hyperkinetic disorder will be invited to take part in a randomized double-blind trial of methylphenidate versus placebo lasting 16 weeks. Medication dosage for methylphenidate will be individually optimized, balancing reduction in hyperkinetic symptoms against side effects. Three dose levels of immediate release medication will be tried, corresponding to 0.5 mg/kg, 1.0 mg/kg and 1.5 mg/kg daily dose in three divided doses (with the three doses corresponding to 40% in the morning, 40% at lunchtime and 20% after school of the total daily dose). Selection of optimal dose will be based on adverse effects and behavioural response. Treatment response will be determined by comparing baseline behaviour with that at 16 weeks. At the end of the 16 weeks, children will be unblended. Those receiving placebo will have the opportunity to commence active medication with the same dose titration method. Those receiving active

medication may continue in an open-label trial, with the possibility of an increase in dose up to 2.0 mg/kg if warranted based on adverse effects and behavioural response. The trial will end at 50 weeks post randomization. Primary outcome points are 16 and 50 weeks, with additional measures wherever possible at 8, 12, 26 and 38 weeks. Ascertainment of research subjects occurs via two arms: clinical referral and population screening.

Not part of treatment trial but interventions:
A behavioural manual (written by the team) is given to all families at the time of eligibility assessment.
Where children have sleep problems, their parents are given a manual on manging sleep problems (standard manual written by Paul Montgomery).
Where sleep problems are ongoing, children may be given melatonin, commencing with 4 mg dose and continuing in weekly 3 mg increments up to 8 mg.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Conners parent and teach questionnaires, short form: ADHD and hyperactivity indices

Key secondary outcome(s))
1. Adverse events (other behaviours questionnaire plus any others noted)
2. Aberrant behaviour questionnaire
3. Quality of Life (Cadfield)
4. Parental Resport on Neuropsychiatric Symptoms (PONS)

Completion date
31/05/2007

Eligibility

Key inclusion criteria
1. Diagnosis of International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10) hyperkinetic disorder
2. Full-scale IQ 30-69 or age equivalent estimate
3. Living in catchment area of one of the participating centres
4. Child in stable care situation
5. Child regularly attending school (more than 75% of last school term)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Child currently in another trial of psychoactive medication
2. Household member with recent diagnosis of substance abuse
3. Severe limitation of child's mobility
4. Presence of a degenerative disorder
5. Medical conditions precluding methylphenidate as treatment of first choice, including:
a. Poorly controlled or uncontrolled epilepsy
b. Presence of tics or Tourette disorder
c. History of psychotic, bipolar or severe obsessive compulsive disorder
d. Child on neuroleptic medication (must be withdrawn for 2 months prior to trial assessment)
e. History of intolerance to stimulant medication
f. Child poses a significant risk of suicidal or homicidal behaviour
6. Another child in the family/household already enrolled in this study
7. Ongoing child protection concerns

Date of first enrolment
01/06/2004

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Professor of Child and Adolescent Psychiatry
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

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	results	01/05/2013		Yes	No